	Proposed Pack Size	10 ml-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	HEPAFOS INJECTION (063574)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
748	Case Category	Routine (Sabahat Zehra)
	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	(MV7-L1D-V1NH, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**PRONEX-4 INJECTION**
	Label Claim	Each ml contains: 2 Phenoxy-2 Methyl-2 Propionic acid ..... 100mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	HEPAFOS INJECTION (063574)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
749	Case Category	Routine (Sabahat Zehra)

	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	(SQB-J3S-X9B4, 2026-03-01)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**BRIFITO INJECTION**
	Label Claim	Each ml contains Diminazene Aceturate ..... 105mg Antipyrine ..... 131mg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Pyraminol Injection. (075676)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
750	Case Category	Routine (Sabahat Zehra)
	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	(S9E-YNQ-P6D2, 2026-02-25)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**GENCIN -10 INJECTION 100 ML**
	Label Claim	: Each ml contains: Gentamicin Sulphate ..... 100mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	Genster 10 Injection (111395)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility

		demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
751	Case Category	Routine (Sabahat Zehra)
	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	(8PT-ZMZ-J9Z5, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**MDINE 33.33% INJECTION**
	Label Claim	Each ml contains: SULFADIMIDINE SODIUM BP ..... 333.33mg (BP Specs.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	SULPHAGOLD INJECTION (049693)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
752	Case Category	Routine (Sabahat Zehra)
	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	(X9D-5RH-VX4Y, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**MIDINE 33.33% INJECTION**
	Label Claim	Each ml contains: SULFADIMIDINE SODIUM BP ..... 333.33mg (BP Specs.)
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	250 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	SULPHAGOLD INJECTION (049693)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	As per letter No. F. 5-6/2021-Lic dated 31 Janurary, 2024. firm has been granted approval of Liquid Injection (General) vet, Liquid Injection (Steriod) vet firm has applied pack size of 250ml. The said letter suggest that the firm has approval only for SVP. Therefore, firm may be advised to regularize/ obtain requisite approval for the relevant section (LVP) through Licensing Division before the approval of applied formulation. Submitted for consideration of Board, please.	
	Decision	
	Deferred Deferred for the clarification of section approval from Licensing Division.	
753	Case Category	Routine (Sabahat Zehra)
	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	(3DR-6PM-N6TZ, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**DRAXXIN INJECTION 100 ML**
	Label Claim	Each ml contains: Trimethoprim ..... 80mg Sulphadiazine.....400mg (As per Innovaror's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	BERSAZINE INJECTION (097860)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

754	Case Category	Routine (Sabahat Zehra)
	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	(7YE-LQD-4DEQ, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**DRAXXIN INJECTION 50 ML**
	Label Claim	Each ml contains: Trimethoprim ..... 80mg Sulphadiazine.....400mg (As per innovator's specifications.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	Zintran Injection (063568)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
755	Case Category	Routine (Sabahat Zehra)
	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	(919-TZS-HX1E, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**DRAXXIN INJECTION 10 ML**
	Label Claim	: Each ml contains: Trimethoprim ..... 80mg Sulphadiazine.....400mg (As per innovator's specifications.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ml-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	Zintran Injection (063568)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
756	Case Category	Routine (Sabahat Zehra)
	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	(ZZ1-E2L-7SM8, 2026-03-01)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**VITOFIT INJECTION**
	Label Claim	Each ml contains Vitamin B1HCl .....5mg Vitamin B2 Sodium Phosphate.....2.5mg Vitamin B6 (HCl)..... 2.5mg Nicotinamide.....37.5mg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Thiaprin Injection. (022185)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
757	Case Category	Routine (Sabahat Zehra)
	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	(TMH-D5U-W59H, 2026-02-23)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**ZANIDE PLUS SUSPENSION**
	Label Claim	Each ml contains: Oxyclozanide.....34.0 mg Sodium Selenite.....0.35 mg Cobalt Chloride.....0.75 mg (As Per innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	ZALVET PLUS SUSPENSION (REG NO. 031492)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 litre pack size.	
758	Case Category	Routine (Sabahat Zehra)
	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	(NA5-RAV-R8NS, 2026-03-01)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**CYNOPIC-500 INJECTION**
	Label Claim	Each ml contains (USP Spec.) Cyanocobalamin..... 500µg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	AMVIT-250 INJECTION Reg. # (109913)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The

		Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
759	Case Category	Routine (Sabahat Zehra)
	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	(23J-1QT-EJ4S, 2026-02-22)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**BENTEL 25 ORAL LIQUID**
	Label Claim	EACH ML CONTAINS: - Febantel.....25MG. (As per Innovator's Spcification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Febensel Suspension (REG NO. 058715)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
760	Case Category	Routine (Sabahat Zehra)
	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	(YA5-UQS-7BHQ, 2026-02-25)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**INTER-SPECTIN INJECTION 100 ML**
	Label Claim	: Each ml contains: Lincomycin as Hcl ..... 50mg Spectinomycin as Hcl..... 100mg (As

		Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	Spectolin 5/ 10% INJECTION (052308)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
761	Case Category	Routine (Sabahat Zehra)
	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	(SZN-V82-ASJQ, 2026-03-01)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**INTER-SPECTIN INJECTION 10 ML**
	Label Claim	Each ml contains: Lincomycin (HCl) ..... 50mg Spectinomycin as HCl..... 100mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ml-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Spectolin 5/ 10% INJECTION (052308)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

762	Case Category	Routine (Sabahat Zehra)
	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	(4Y3-V4L-EUG6, 2026-02-25)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**INTER-SPECTIN INJECTION 50 ML**
	Label Claim	Each ml contains: Lincomycin as Hcl ..... 50mg Spectinomycin as Hcl..... 100mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	Spectolin 5/ 10% INJECTION (052308)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
763	Case Category	Routine (Sabahat Zehra)
	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	(1QY-VMY-PN6M, 2026-02-22)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**SYSTAZOLE ORAL SUSPENSION**
	Label Claim	Each 100ml contains: Oxfendazole..... 2.265 g (USP specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Year(s)at Room Temperature
	For generic drugs (me-too Status)	HANSENID ORAL SUSLPENSION (REG NO. 102247)
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--

	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
764	Case Category	Routine (Sabahat Zehra)
	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	(P6U-HS2-7YUH, 2026-02-25)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**GENCIN 10 INJECTION 10 ML**
	Label Claim	Each ml contains: Gentamicin Sulphate ..... 100mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	Genster 10 Injection (111393)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
765	Case Category	Routine (Sabahat Zehra)
	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	(PXD-8W5-3RD8, 2026-02-25)
	Detail of Fee Submitted	38700, 2026-02-17,

	The proposed proprietary name / brand name	**GENCIN -10 INJECTION 50 ML**
	Label Claim	Each ml contains: Gentamicin Sulphate ..... 100mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	Genster 10 Injection (111394)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
766	Case Category	Routine (Sabahat Zehra)
	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	(BL6-5RN-X3AH, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**MIDINE 33.33% INJECTION**
	Label Claim	: Each ml contains: SULFADIMIDINE SODIUM BP ..... 333.33mg (BP Specs.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	500 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	SULPHAGOLD INJECTION (049693)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	As per letter No F.5-6/2021-Lic dated 31st January,2024 firm has been granted approval of Liquid Injection Section vet (General), firm has applied pack size of 500ml. The said letter suggest that the firm has approval only for SVP. Therefore, firm may be advised to regularize/ obtain requisite approval for the rrelevant section (LVP) through Licensing Division before the approval of applied formulation. Submitted for consideration of Board,please.	

	Decision	
	Deferred Deferred for the clarification of section approval from Licensing Division.	
767	Case Category	Routine (Sabahat Zehra)
	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	(E5H-3S6-6AT1, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-02-23,
	The proposed proprietary name / brand name	**Aclowan Injection 100ml**
	Label Claim	Each mL Contains: Aceclofenac.....25mg
	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 heat and light.
	For generic drugs (me-too Status)	10ml, 20ml and 50ml Available & 100ml is Not Available
	Pharmacotherapeutic Group of (API)	Anti-inflammatory, Anti-Pyretic and Analgesic
	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	Present
	Evaluation Remarks	
	Aclowan Injection" Pack Size 50ml" already registered, Firm has submitted application for pack size of 100ml	
	Decision	
	Approved	
768	Case Category	Routine (Sabahat Zehra)
	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	(YJH-G2N-LLRJ, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2024-05-08,
	The proposed proprietary name / brand name	**Fomit 20mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Famotidine.....20mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	Acicon Tablet 20mg by M/s Barrett Hodgson Pakistan (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Antiulcerative
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	
	Detail of stability batches of drug product	FD-01, FD-02, FD-03
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Famto 20mg Tablets (Shaigan Pharmaceutical (Pvt) Ltd Batch No: 161
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	FM/08/00/017, FM/08/00/018 , FM/08/00/019
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
769	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Winlet Pharmaceuticals (Pvt) Ltd.** 30-Km, Lahore Sargodha Raod, Sargodha **(000874)**
	Application Form Dy. No / Tracking ID & date of submission	(ZVJ-5HS-VVG6, 2024-08-23)
	Detail of Fee Submitted	30000.0, 2024-07-25,
	The proposed proprietary name / brand name	**famlet 20**
	Label Claim	Each film coated tablet contains; Famotidine 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2X10-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 °C
	For generic drugs (me-too Status)	famot 20
	Pharmacotherapeutic Group of (API)	Antiulserative
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	MS RAKSHIT PHARMACEUTICALS LIMITED
	Detail of stability batches of drug product	T-001, T-002, T-003
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Famot 20mg Tablet by Shaigan Pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	FT/05/12/001, FT/05/12/002, FT/05/12/003
	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product/11523/
	GMP status of the firm	Present
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	Decision	

	Approved	
770	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Winlet Pharmaceuticals (Pvt) Ltd.** 30-Km, Lahore Sargodha Raod, Sargodha **(000874)**
	Application Form Dy. No / Tracking ID & date of submission	(EW3-2Q8-5L9B, 2024-08-23)
	Detail of Fee Submitted	30000.0, 2024-07-25,
	The proposed proprietary name / brand name	**famlet 40**
	Label Claim	Each film coated tablet contains; Famotidine..... 40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2X10-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 °C
	For generic drugs (me-too Status)	famot 40mg
	Pharmacotherapeutic Group of (API)	Antiulcerative
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	MS RAKSHIT PHARMACEUTICALS LIMITED
	Detail of stability batches of drug product	T-001 , T-002, T-003
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Famot 40mg Tablet by Shaigan Pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	FT/05/12/001 , FT/05/12/002, FT/05/12/003
	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product/11524/
	GMP status of the firm	Present
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
771	Case Category	Routine (Sabahat Zehra)
	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	(6Z4-NN6-86MS, 2024-10-09)
	Detail of Fee Submitted	93000.0, 9400 2024-09-24, 2026-07-29
	The proposed proprietary name / brand name	**Fixaler**
	Label Claim	Each 5ml contain: Fexofenadine HCl eq. to Fexofenadine 30mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	30mL, 60mL, 90mL, 10-As per SRO
	Shelf Life (Unit)	24 Year(s)store between 20º and 25ºC
	For generic drugs (me-too Status)	Telfast by Hoechst Pakistan Limited (formerly Sanofi-Aventis Pakistan Limited)
	Pharmacotherapeutic Group of (API)	Antihistamine
	Name, address of Manufacturing site:	Genix Pharma Private Limited-44, 45-B Korangi Creek Road, Karachi-75190, Pakistan -
	Name & address of API manufacturer	AMI LIFESCIENCES PVT. LTD.,
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Manufacturer: AMI Life Sciences Private Limited Manufacturing Site: Block No.82/B, ECP Road, At & Post: Karakhadi-391450, Taluka: Padra, District: Vadodara, Gujarat, INDIA.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CHILDREN'S ALLERGY FEXOFENADINE HICI ORAL SUSPENSION 30mg/5ml (B# A581255) byTARO PHARMACEUTICALS U.S.A,Inc..
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	FXO/20020809 , FXO/20030809 , FXO/20040809
	The status in reference regulatory authorities	Children’s Allergy Fexofenadine HCl Oral Suspension 30mg/5mL by TARO Pharmaceutical
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	It was observed that certain chromatograms have been repeated multiple times across different stability studies/batches. The same chromatographic data appear to have been used for the following batches and stability conditions: Batch No. 24SB-263-03 – Real-Time Stability Batch No. 24SB-261-01 – Accelerated Stability Batch No. 24SB-262-02 – Accelerated Stability Batch No. 24SB-263-03 – Accelerated Stability	
	Decision	
	Deferred For clarification from the firm why they have not submitted data of cross referred product of M/s. Genix Pharma, Karachi.	
772	Case Category	Contract Manufacturing (Saima Hussain)
	Name, address of Applicant.	**Cell Health Sciences,** Plot No 217, Industrial Triangle, Kahuta Road, Islamabad **(000711)**
	Application Form Dy. No / Tracking ID & date of submission	(RJV-2J5-W4Z7, 2024-08-20)
	Detail of Fee Submitted	75000.0, 2024-08-02,
	The proposed proprietary name / brand name	**Fenocell 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 YearStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-

	Name & address of API manufacturer	Shandong Chenghuishuangda Pharmaceutical Co.,Ltd Add: Economic Development Zone, Pingyuan County, Dezhou, Shandong, China
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	KERENDIA(finerenone) 10mg tablet of M/s Bayer Healthcare Pharmaceutical Inc., Whippany, NJ 07981 Manufactured in Germany (USFDA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Registration Board in its 353rd meeting approved the product Finron 10mg Tablet (Finerenone) in the name of M/s. Wimits Pharmaceuticals Pvt. Ltd 129-SunderIndustrial Estate, Lahore. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Firm shall submit fee for pre-registration variation as the latest fee SRO prior the issuance of Registration Letter.	
773	Case Category	Contract Manufacturing (Saima Hussain)
	Name, address of Applicant.	**Cell Health Sciences,** Plot No 217, Industrial Triangle, Kahuta Road, Islamabad **(000711)**
	Application Form Dy. No / Tracking ID & date of submission	(5DV-U2Z-3SBA, 2024-08-22)
	Detail of Fee Submitted	75000.0, 2024-08-05,
	The proposed proprietary name / brand name	**Fenocell 20mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Finerenone.....20mg
	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 YearStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	Name & address of API manufacturer	Shandong Chenghuishuangda Pharmaceutical Co.,Ltd Add: Economic Development Zone, Pingyuan County, Dezhou, Shandong, China
	Detail of stability batches of drug product	

	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	KERENDIA(finerenone) 20mg tablet of M/s Bayer Healthcare Pharmaceutical Inc., Whippany, NJ 07981 Manufactured in Germany (USFDA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Registration Board in its 353rd meeting approved the product Finron 20mg Tablet (Finerenone) in the name of M/s. Wimits Pharmaceuticals Pvt. Ltd 129-SunderIndustrial Estate, Lahore. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Firm shall submit fee for pre-registration variation as the latest fee SRO prior the issuance of Registration Letter.	
774	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	(9V1-69M-RT1X, 2024-07-23)
	Detail of Fee Submitted	75000.0, 2024-06-25,
	The proposed proprietary name / brand name	**Finro 10mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Finerenone.....10mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°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. -
	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	
	Registration Board in its 353rd meeting approved the product Finrox 10mg Tablet (Finerenone) on Form-5F in the name of M/s. Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Estate, Hattar. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Firm shall submit fee for pre-registration variation as the latest fee SRO prior the issuance of Registration Letter.	
775	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	(73V-LVU-4MWS, 2024-08-20)
	Detail of Fee Submitted	75000.0, 2024-06-25,
	The proposed proprietary name / brand name	**Finro 20mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Finerenone.....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 YearStore below 25°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. -
	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	
	Registration Board in its 353rd meeting approved the product Finrox 20mg Tablet (Finerenone) on Form-5F in the name of M/s. Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Estate, Hattar. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Firm shall submit fee for pre-registration variation as the latest fee SRO prior the issuance of Registration Letter.	
776	Case Category	New Section (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	(STY-J2N-4SZJ, 2026-04-08)
	Detail of Fee Submitted	38700, 2025-12-19,
	The proposed proprietary name / brand name	**Mupicin 2% Ointment**
	Label Claim	Each gram of ointment contains: Mupirocin ..... 20mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	15gm-Controlled
	Shelf Life (Unit)	2 YearStore below 30 degree centigrade
	For generic drugs (me-too Status)	Mupir Ointment (Manufacturer: Valor Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic group: Antibiotics and chemotherapeutics for dermatological use. ATC code: D06AX09
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	Attached in Module 3 sub section 3.2.P.8.3
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in stability annexures
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP not applicable, PE attached in Module 3.2.P.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Module 3 sub section 3.2.S.7.3
	The status in reference regulatory authorities	Bactroban 2% Ointment (MHRA Approved)
	GMP status of the firm	Attached in Module 1
	Evidence of approval of manufacturing facility	Attached in Module 1 Sub-section 1.3.5
	Evaluation Remarks	
	Decision	
	Approved	

777	Case Category	Export Facilitation (Saima Hussain)
	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	(QE7-MB5-V2RW, 2025-10-03)
	Detail of Fee Submitted	38700, 2025-09-18,
	The proposed proprietary name / brand name	**Ongene Orodispersible 8mg Tablet**
	Label Claim	Each Orodispersible tablet contains: Ondansetron ..... 8mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x14's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Dysit ODT 8mg Tablet of Wimits Pharmaceuticals Pvt. Limited was approved in 345th meeting of the registration board
	Pharmacotherapeutic Group of (API)	Antiemetics and antinauseants, Serotonin (5-HT3) antagonists ATC code: A04AA01
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	8ONDPD01/24, 8ONDPD02/24 and 8ONDPD03/24 batches-Attached in Module 3-P.8.3
	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC attached in Module 3-Page no 2299
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the product Mint Ondansetron-ODT--Attached in module 3
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (upto 6 months) and Real time stability data at zone IVB (upto 72 months)-Attached in Module 3-S.7.3
	The status in reference regulatory authorities	ZOFRAN ODT 8MG Manufactured for: GlaxoSmithKline Research Triangle Park, NC 27709 by Cardinal Health Blagrove, Swindon, Wiltshire, UK SN5 8RU (USFDA Approved)
	GMP status of the firm	Valid for 3 years (Attached in module 1)
	Evidence of approval of manufacturing facility	Section Approval date is 05-july-2006 (Attached in module 1)
	Evaluation Remarks	
	Decision	
	Approved	
778	Case Category	Export Facilitation (Saima Hussain)
	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	(XP1-MHZ-VWT2, 2025-09-29)
	Detail of Fee Submitted	37000.0, 2025-05-14,
	The proposed proprietary name / brand name	**Velker 40mg Tablet**

	Label Claim	Each film coated tablet contains: Valsartan ..... 40mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 10's-De-Controlled,1 x 14's-De-Controlled,2 x 10's-De-Controlled,2 x 14's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Valtec 40mg Tablet (Manufactured by Tabros Pharma Pvt Ltd)
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), ATC code: C09CA03
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	4VKPD01/25, 4VKPD02/25 & 4VKPD03/25 (Attached in Module 3 P-Part Pg # 1055)
	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC Attached in Module 3 Pg # 1354
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed by Competitor Product "Valtec (Valsartan) 40mg Tablet B # 187" (Attached in Module 3: P-Part Pg # 608)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (up to 6 months) and Long-term on Zone IV-B (up to 60 months) (Attached in Module 3 S-Part Pg # 535)
	The status in reference regulatory authorities	Valsartan Rowa 40 mg film-coated tablets (HPRA Approved)
	GMP status of the firm	Valid for three years (Attached in Module 1 Pg # 39)
	Evidence of approval of manufacturing facility	Section approval date is 05-Jul-2006 (Attached in Module 1: Section 1.3.5 Pg # 42)
	Evaluation Remarks	
	Decision	
	Approved	
779	Case Category	Export Facilitation (Saima Hussain)
	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	(VNG-QYD-JJA9, 2025-10-22)
	Detail of Fee Submitted	38700, 2025-10-15,
	The proposed proprietary name / brand name	**Finera 20mg Tablet**
	Label Claim	Each film-coated tablet contains: Finerenone.....20mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 degree centigrade in a dry place
	For generic drugs (me-too Status)	Finone 20mg Tablet by Getz Pharma (Pvt.) Limited

	Pharmacotherapeutic Group of (API)	Diuretics, Aldosterone antagonists, ATC code: C03DA05
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	2FNPDO1/25, 2FNPDO2/25, 2FNPDO3/25 (Attached in Module 3: Section 3.2.P.8)
	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC attached in Module 3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed by Competitor product "Finone 20mg Tablet B# 001FQ3 (Attached in Module 3)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (6 months) and Long term on Zone IV-A (24 months) (Attached in Module 3: Section 3.2.S.7)
	The status in reference regulatory authorities	Kerendia 20mg Tablets MHRA Approved
	GMP status of the firm	14-March-2025 Valid for 3 years (Attached in Module 1: Section 1.3.4)
	Evidence of approval of manufacturing facility	Section Approval dated: 05-July-2006 (Attached in Module 1: Section 1.3.5)
	Evaluation Remarks	
	Decision	
	Approved	
780	Case Category	Export Facilitation (Saima Hussain)
	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	(NVD-M83-MD32, 2025-10-22)
	Detail of Fee Submitted	38700, 2025-10-15,
	The proposed proprietary name / brand name	**Finera 10mg Tablet**
	Label Claim	Each film-coated tablet contains: Finerenone.....10mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 degree centigrade in a dry place.
	For generic drugs (me-too Status)	Finone 10mg Tablet by Getz Pharma (Pvt.) Limited
	Pharmacotherapeutic Group of (API)	Diuretics, Aldosterone antagonists, ATC code: C03DA05
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	1FNPDO1/25, 1FNPDO2/25, 1FNPDO3/25 (Attached in Module 3: Section 3.2.P.8)
	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC attached in Module 3

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed by Competitor product "Finone 10mg Tablet B# 003FQ2 (Attached in Module 3)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (6 months) and Long term on Zone IV-A (24 months) (Attached in Module 3: Section 3.2.S.7)
	The status in reference regulatory authorities	Kerendia 10 mg Tablets MHRA Approved
	GMP status of the firm	14-March-2025 Valid for 3 years (Attached in Module 1: Section 1.3.4)
	Evidence of approval of manufacturing facility	Section Approval date 05-July-2006 (Attached in Module 1: Section 1.3.5)
	Evaluation Remarks	
	Decision	
	Approved	
781	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	**Pacific Pharmaceutical Ltd** 30 km Multan Road Lahore **(000295)**
	Application Form Dy. No / Tracking ID & date of submission	(7TV-AP5-EZBH, 2025-09-29)
	Detail of Fee Submitted	37000.0, 2025-02-14,
	The proposed proprietary name / brand name	**EPIZET 200mg Tablets**
	Label Claim	Each uncoated Tablet contains: Carbamazepine..... 200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,30's-As per SRO,50’s-As per SRO
	Shelf Life (Unit)	2 YearStore below 250C. Store in the original package in order to protect from light and moisture.
	For generic drugs (me-too Status)	a) Brand name: Teril b) Strength: 200mg c) Manufacturer: Martin Dow d) Dosage form: Tablet e) Pack size: 5 x 10’s f) Pack price: NA
	Pharmacotherapeutic Group of (API)	Antiepileptic, neurotropic and psychotropic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Jiuzhou Pharmaceutical Co., Ltd. Address: 99 Waisha Road, Jiaojiang District, Taizhou City, Zhejiang Province, 318000, China.
	Detail of stability batches of drug product	Attached in 3.2.P.8
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Module 1
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in 3.2.P.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided in 3.2.S.7
	The status in reference regulatory authorities	a) Brand name: Carbamazepine b) Strength: 200mg c) Manufacturer: Apotex Inc. d) Dosage form: Tablet e) Pack size: 100’s
	GMP status of the firm	GMP Certified
	Evidence of approval of manufacturing facility	DML & GMP is Attached in Module 1
	Evaluation Remarks	

	Decision	
	Approved	
782	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	**Pacific Pharmaceutical Ltd** 30 km Multan Road Lahore **(000295)**
	Application Form Dy. No / Tracking ID & date of submission	(3TA-D54-XY13, 2025-10-06)
	Detail of Fee Submitted	37000.0, 2025-07-10,
	The proposed proprietary name / brand name	**Pacilinz 400mg Tablet**
	Label Claim	Each Film Coated tablet contains: Linezolid.....400mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-As per SRO
	Shelf Life (Unit)	2 Year15 °C - 30 °C
	For generic drugs (me-too Status)	Nezkil (400mg)
	Pharmacotherapeutic Group of (API)	Anti-bacterial (Oxazolidinones)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Benova Labs Private Limited #13-1-183/1, Plot No. 69, Snehapuri Colony, Motinagar, Hyderabad-500018, Telangana, INDIA
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	Attached
	GMP status of the firm	VALID
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	Decision	
	Approved	
783	Case Category	Routine (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	(HG7-AH6-54B4, 2025-09-29)
	Detail of Fee Submitted	93000.0, 2025-04-30,
	The proposed proprietary name / brand name	**Relagolin**
	Label Claim	Each film coated tablet contains: Relugolix.....40mg Estradiol.....1mg Norethindrone Acetate.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,28's-As per SRO

Shelf Life (Unit)	2 Yearstore below 30°C in a cool and dry place
For generic drugs (me-too Status)	Nil
Pharmacotherapeutic Group of (API)	Anti gonadotropin releasing hormones
Name, address of Manufacturing site:	Platinum Pharmaceuticals (Pvt) Ltd.,-Plot no. A-20, North Western Industrial Zone, Bin Qasim Authority, Karachi-75020, Pakistan.-
Name & address of API manufacturer	No. 9A1, Tianheng Road, Changjia Town, Gaoqing County, Zibo City,Shandong Province., China.,Plot.no.K2 ,M.I.D.C, Tarapur, Boisar – 401506, district: Palghar, state: Maharastra-India
Detail of stability batches of drug product	Accelerated Stability Study {0, 3,6 months (completed)}, Long term / Real time stability study{0,3,6) months (completed)}
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	pharmaceutical equivalence and CDP has been provided,
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	provided
The status in reference regulatory authorities	Food & Drug administration (FDA)
GMP status of the firm	valid
Evidence of approval of manufacturing facility	attached

Evaluation Remarks

Sr.no.	Observations	Response of the Firm
1.	Justify the rationale for not performing the assay testing of the drug substance Estradiol in accordance with the claimed specification, i.e., the USP monograph for Estradiol, since the procedure given in section 3.2.S.4.2 by the drug product manufacturer is not in accordance with USP. Correlate the solution preparation method adopted by the drug product manufacturer during assay verification studies of the drug substance with the sample preparation procedure specified in the USP monograph for Estradiol. Furthermore, it is noted that the drug product manufacturer has not prepared or utilized the internal standard as recommended in the USP; this deviation should be justified.	Initially firm replied that, ethod of Estradiol, is available in USP and same method was used for Method Verification and material testing, the USP monograph is attached here for your reference. After the next query, firm confused it with the assay adopted for drug product manufacturer and claimed that their drug product contains three active ingredients (Estradiol, Norethindrone, and Relugolix), and the assay method has been scientifically developed as a simultaneous multi-component method to quantify all three analytes in a single chromatographic run. Due to the significant differences in physicochemical proper es, retention behavior, and detection characteristics of these APIs, the chromatographic conditions (including mobile phase composition, gradient, wavelength, and sample preparation) have been appropriately optimized and are inherently different from the USP monograph for Estradiol alone.
2.	Submit updated stability data of the drug product covering the period from the 9th month up to the latest available time point, along with complete performance reports, raw data	Firm submit the stability data of drug product till 18th months without the raw data sheets and relevant chromatograms.

	sheets, and corresponding chromatograms.	
3.	Provide the compliance records of the HPLC software in accordance with 21 CFR Part 11 requirements, including audit trail reports for product testing, as these documents were not included in the pages referenced in your previous response.	The firm has submitted an audit trail report mentioning date and time (08/08/2025 at 08:43:14 PM), which does not correspond to the actual date of analysis for any time point of the drug product stability studies.

Registration Board in its 357th meeting deferred the case for submission of following shortcomings.: Perform the assay testing and verification studies of drug substance estradiol in accordance with the USP by the drug product manufacturer and accordingly submit the report along with raw data sheets and chromatograms. Submit the raw data sheets, relevant chromatograms, and complete audit trail/system logs for the updated stability data of the drug product up to 18 months. Provide the complete audit trail and data logs for all HPLC analysis conducted during the stability studies of the drug product.

Sr.no.	Decision of Registration Board	Response of the Firm
1.	Perform the assay testing and verification studies of drug substance estradiol in accordance with the USP by the drug product manufacturer and accordingly submit the report along with raw data sheets and chromatograms.	Firm submitted the revised assay verification studies of API estradiol in accordance with USP.
2.	Submit the raw data sheets, relevant chromatograms, and complete audit trail/system logs for the updated stability data of the drug product up to 18 months.	Firm submitted the updated stability data of the drug product along with requisite documents.
3.	Provide the complete audit trail and data logs for all HPLC analysis conducted during the stability studies of the drug product.	Firm submit the audit trail report.

Decision

Approved

Firm shall submit fee for pre-registration variation as the latest fee SRO prior the issuance of Registration Letter.

784	Case Category	Routine (Saima Hussain)
	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	(D2A-PZB-57Q1, 2025-10-02)
	Detail of Fee Submitted	75000.0, 2025-04-22,
	The proposed proprietary name / brand name	**Regolix-EN Tablet**
	Label Claim	Each film-coated tablet contains: Relugolix.....40mg Estradiol.....1mg Norethindrone Acetate.....0.5mg
	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 YearStore below 30°C

For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	H01CC54 (anti-gonadotropin releasing hormone)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Shakti Lifescience Pvt. Ltd.,Shandong Kehui Pharmaceutical Co. Ltd
Detail of stability batches of drug product	Attached
Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	attached
The status in reference regulatory authorities	Myfembree (USFDA)
GMP status of the firm	Valid (attached)
Evidence of approval of manufacturing facility	Valid (attached)

Evaluation Remarks

Sr.no.	Observations	Response of the Firm
1.	Justify the rationale for not performing the assay testing of the drug substance Estradiol in accordance with the claimed specification, i.e., the USP monograph for Estradiol, since the procedure given in section 3.2.S.4.2 by the drug product manufacturer is not in accordance with USP. Correlate the solution preparation method adopted by the drug product manufacturer during assay verification studies of the drug substance with the sample preparation procedure specified in the USP monograph for Estradiol. Furthermore, it is noted that the drug product manufacturer has not prepared or utilized the internal standard as recommended in the USP; this deviation should be justified.	Initially firm replied that, ethod of Estradiol, is available in USP and same method was used for Method Verification and material testing, the USP monograph is attached here for your reference. After the next query, firm confused it with the assay adopted for drug product manufacturer and claimed that their drug product contains three active ingredients (Estradiol, Norethindrone, and Relugolix), and the assay method has been scientifically developed as a simultaneous multi-component method to quantify all three analytes in a single chromatographic run. Due to the significant differences in physicochemical proper es, retention behavior, and detection characteristics of these APIs, the chromatographic conditions (including mobile phase composition, gradient, wavelength, and sample preparation) have been appropriately optimized and are inherently different from the USP monograph for Estradiol alone.
2.	Submit updated stability data of the drug product covering the period from the 9th month up to the latest available time point, along with complete performance reports, raw data sheets, and corresponding chromatograms.	Firm submit the stability data of drug product till 18th months without the raw data sheets and relevant chromatograms.
3.	Provide the compliance records of the HPLC software in accordance with 21 CFR Part 11 requirements, including audit trail reports for product testing,	The firm has submitted an audit trail report mentioning date and time (08/08/2025 at 08:43:14 PM), which does not correspond to the actual date of analysis for any time point of the drug product stability studies.

	as these documents were not included in the pages referenced in your previous response.	

Registration Board in its 357th meeting deferred the case for submission of following shortcomings.: Perform the assay testing and verification studies of drug substance estradiol in accordance with the USP by the drug product manufacturer and accordingly submit the report along with raw data sheets and chromatograms. Submit the raw data sheets, relevant chromatograms, and complete audit trail/system logs for the updated stability data of the drug product up to 18 months. Provide the complete audit trail and data logs for all HPLC analysis conducted during the stability studies of the drug product.

Sr.no.	Decision of Registration Board	Response of the Firm
1.	Perform the assay testing and verification studies of drug substance estradiol in accordance with the USP by the drug product manufacturer and accordingly submit the report along with raw data sheets and chromatograms.	Firm submitted the revised assay verification studies of API estradiol in accordance with USP.
2.	Submit the raw data sheets, relevant chromatograms, and complete audit trail/system logs for the updated stability data of the drug product up to 18 months.	Firm submitted the updated stability data of the drug product along with requisite documents.
3.	Provide the complete audit trail and data logs for all HPLC analysis conducted during the stability studies of the drug product.	Firm submit the audit trail report.

Decision

Approved

Firm shall submit fee for pre-registration variation as the latest fee SRO prior the issuance of Registration Letter.

785		
	Case Category	Routine (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	(44V-DEL-QX8A, 2024-10-18)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-10-09
	The proposed proprietary name / brand name	**Vonzan**
	Label Claim	Each film coated tablets contains: Vonoprazan as fumarate 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's 20's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Voniza tablet Hilton pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jiangxi synergy pharmaceuticals C. 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	USFDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Firm shall submit fee for pre-registration variation as the latest fee SRO prior the issuance of Registration Letter.	
786	Case Category	Routine (Saima Hussain)
	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	(J71-A8B-N496, 2024-10-22)
	Detail of Fee Submitted	37000.0, 2024-10-09,
	The proposed proprietary name / brand name	**Mufidar XR Tablets 15mg**
	Label Claim	Each film-coated extended-release tablet contains: Darifenacin Hydrobromide equivalent to Darifenacin .....15mg.
	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 Sunlight and moisture
	For generic drugs (me-too Status)	Dericin 15mg Tablet by Pacific Pharmaceutical Ltd.
	Pharmacotherapeutic Group of (API)	Antimuscarinics (M3 Muscarinic Receptor Blocker)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batch Number: DAR-548-06/23 Batch size: 5000 Tablets Batch Number: DAR-573-07/23 Batch size: 5000 Tablets Batch Number: DAR-574-08/23 Batch size: 5000 Tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is attached.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have performed against Esmelex tablet.
	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	Emselex Tablets 15mg by DREHM Pharma GmbH, Austria
	GMP status of the firm	GMP certificate dated 24th January,2024 is submitted

	Evidence of approval of manufacturing facility	GMP certificate dated 24th January,2024 is submitted, mentioned that firm has tablet (general) section.
	Evaluation Remarks	
	Decision	
	Approved	
787	Case Category	Routine (Saima Hussain)
	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	(W94-5TS-PYPS, 2024-10-22)
	Detail of Fee Submitted	75000.0, 2024-10-09,
	The proposed proprietary name / brand name	**Mufidar XR Tablets 7.5mg**
	Label Claim	Each film-coated extended-release tablet contains: Darifenacin Hydrobromide equivalent to Darifenacin 7.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's -De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30C . Protect from Sunlight and moisture.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Antimuscarinics (M3 Muscarinic Receptor Blocker)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has performed against the Esmelex Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted till 24months.
	The status in reference regulatory authorities	Emselex Tablets 7.5mg by DREHM Pharma GmbH, Austria , Europe
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
788	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	**Pacific Pharmaceutical Ltd** 30 km Multan Road Lahore **(000295)**
	Application Form Dy. No / Tracking ID & date of submission	(41P-RM8-5NY6, 2025-10-02)

	Detail of Fee Submitted	37000.0, 2025-07-10,
	The proposed proprietary name / brand name	**Fosocin 3g Sachet**
	Label Claim	Each sachet contains Fosfomycin Trometamol equivalent to Fosfomycin 3g
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year15 °C - 30 °C
	For generic drugs (me-too Status)	Focin Ultra (3g) 1 Sachet
	Pharmacotherapeutic Group of (API)	Phosphonic Antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Guilin Hwasun Pharamaceutical Co,.LTD
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	Attached
	GMP status of the firm	VALID
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	Decision	
	Approved	
789	Case Category	Routine (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	(GUL-X7T-TVQY, 2024-08-20)
	Detail of Fee Submitted	75000.0, 2024-05-24,
	The proposed proprietary name / brand name	**Unigraf**
	Label Claim	Each Extended release Tablet contains: Tacrolimus.....0.75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 Year(s)store in a cool and dry place below 30°C
	For generic drugs (me-too Status)	Nil
	Pharmacotherapeutic Group of (API)	Immunosuppressant L04AD02
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s North China Pharmaceutical Huasheng Co., Ltd. No.8 Yangzi Road, Shi- jiazhuang Economic and Technological De- velopment Zone, Hebei 052160, China
	Detail of stability batches of drug product	Stability data of three batches of 100 tablets each is submitted.

	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-5 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have performed against the innovator product envarsus XR tablet
	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	Food & Drug Administration (FDA)
	GMP status of the firm	GMP certificate dated 26-06-2023 is submitted
	Evidence of approval of manufacturing facility	GMP certificate dated 26-06-2023 is submitted, mentioned that firm has tablet (general) section.
	Evaluation Remarks	
	Decision	
	Approved Firm shall submit fee for pre-registration variation as the latest fee SRO prior the issuance of Registration Letter.	
790	Case Category	Routine (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	(TM1-UT8-QDWD, 2024-08-28)
	Detail of Fee Submitted	75000.0, 2024-05-24,
	The proposed proprietary name / brand name	**Unigraf ER Tablet**
	Label Claim	Each Extended release Tablet Contains: Tacrolimus.....1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,30'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)	Nil
	Pharmacotherapeutic Group of (API)	Immunosuppressant L04AD02
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s North China Pharmaceutical Huasheng Co., Ltd. No.8 Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei 052160, China
	Detail of stability batches of drug product	Stability data of three batches of 100 tablets each is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-5 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have performed against the innovator product envarsus XR tablet
	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	Food and Drug Administration
	GMP status of the firm	GMP certificate dated 26-06-2023 is submitted
	Evidence of approval of manufacturing facility	GMP certificate dated 26-06-2023 is submitted, mentioned that firm has tablet (general) section.

	Evaluation Remarks	
	Decision	
	Approved Firm shall submit fee for pre-registration variation as the latest fee SRO prior the issuance of Registration Letter.	
791	Case Category	Routine (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	(5ZJ-EBT-WZGS, 2024-07-31)
	Detail of Fee Submitted	75000.0, 2024-05-24,
	The proposed proprietary name / brand name	**Unigraf**
	Label Claim	Each Extended release Tablet Contains: Tacrolimus.....4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place below 30°C
	For generic drugs (me-too Status)	Nil
	Pharmacotherapeutic Group of (API)	Immunosuppressant L04AD02
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s North China Pharmaceutical Huasheng Co., Ltd. No.8 Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei 052160, China
	Detail of stability batches of drug product	Stability data of three batches of 100 tablets each is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-5 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have performed against the innovator product envarsus XR tablet
	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	Food & Drug Administration (FDA)
	GMP status of the firm	GMP certificate dated 26-06-2023 is submitted
	Evidence of approval of manufacturing facility	GMP certificate dated 26-06-2023 is submitted, mentioned that firm has tablet (general) section.
	Evaluation Remarks	
	Decision	
	Approved Firm shall submit fee for pre-registration variation as the latest fee SRO prior the issuance of Registration Letter.	
792	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	(HL3-MEL-JZHM, 2025-03-27)
Detail of Fee Submitted	300000.0, 2024-12-27,
The proposed proprietary name / brand name	**Gadomine-15ml**
Label Claim	Each ml contains: Gadopentetate Dimeglumine 469mg. 7.04g/ Unit of 15ml
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's (15ml)-As per SRO
Shelf Life (Unit)	36 Year(s)Store at controlled room temperature 20°-25°C., excursion permitted to 15-30°C. Do not Freeze. Protect from light.
For generic drugs (me-too Status)	Registration Number: 011539 Brand Name: Magnevist Injection Dosage Form: Injection Registration Date: 2/7/1991 Composition: GADOPENTETIC DIMEGLUMINE 469.01MG Market Authorisation Holder: Bayer Pakista
Pharmacotherapeutic Group of (API)	Gadolinium based contrast agent
Name, address of Manufacturing site:	Unijules Life Sciences Limited-D-82, Cross road no 4 A, MIDC Area, Hingna, Nagpur – 440028 (M.S), India-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE has performed against the comparator Product Gadopentetate Dimeglumine Injection USP 469 mg/ml of M/s. Unique Pharmaceutical Laboratories Batch no. 10023010 Mfg.date: 04-2023
Name, address of Marketing Authorization Holder:	Unijules Life Sciences Limited, D-82, Cross road no 4 A, MIDC Area, Hingna, Nagpur – 440028 (M.S), India, India
Details of Certificates (CoPP/FSC/cGMP):	GMP certificate dated 29th Sep,2022 issued by Food & Drug Administration,Bandra Mumbai.
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm submitted the stability data of drug substance
The status in reference regulatory authorities	MAGNEVIST® MAGNEVIST (gadopentetate dimeglumine) injection, for intravenous use Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ 07981 Manufactured in Germany UDFDA Approved

Evaluation Remarks

CoPP no. COPP/CERT/ND/147887/2025/11/53997/259700 dated 28th Feb,2025 issued by Food and Drug Administration, Bandra, Mumbai

Sr.no.	Observations	Response of the firm

1.	The innovator product specifies a fixed, pre-determined quantity of diethylenetriamine pentaacetic acid. In contrast, your formulation describes this excipient as "q.s.", with a calculation formula provided in the manufacturing procedure to determine the required quantity at the time of production. Kindly clarify this difference from innovator. Furthermore, it is noted that the same calculation formula was not applied for determining the quantity during the manufacturing of stability batches, as per the submitted Batch Manufacturing Records (BMRs). Please justify the rationale for not adopting the same method.	In summary, Pentetic Acid is used as a chelating agent to bind free gadolinium ions and ensure product safety. As per USP, it is permitted within a range of 0.027%–0.04%, hence a fixed quantity is not mandatory. A target value of 0.034% (midpoint of the USP range) is used, and the required quantity is calculated based on batch size and existing content to ensure complete chelation without excess. This approach aligns with USP requirements and focuses on controlling free gadolinium levels rather than maintaining a fixed excipient concentration. The same calculation-based method will be consistently applied in future batches to ensure compliance.

Registration Board in its 357th meeting has decided to defer the application for submission of following: Submit valid and legalized Sole Agency Agreement/letter of Authorization pertaining to the instant applied product. Submit evidence of the reference product approved by relevant regulatory authorities/agencies that does not use a fixed, pre-determined quantity of pentetic acid in its formulation. Instead, the required amount is calculated based on batch size and an amount sufficient to achieve full chelation and to minimize the presence of free gadolinium ions.

Sr.no.	Decision of Registration Board	Response of the Firm
1.	Submit valid and legalized Sole Agency Agreement/letter of Authorization pertaining to the instant applied product.	Firm submitted valid Legalized Letter of Authorization for Gadomine 10ml & 15ml glass vials which is valid until December,2026.
2.	Submit evidence of the reference product approved by relevant regulatory authorities/agencies that does not use a fixed, pre-determined quantity of pentetic acid in its formulation. Instead, the required amount is calculated based on batch size and an amount sufficient to achieve full chelation and to minimize the presence of free gadolinium ions.	The applicant respectfully submits that the quantity of Pentetic Acid incorporated in the manufacture of Gadopentetate Dimeglumine Injection USP 469 mg/mL is not intended to be a fixed formulation quantity, but is scientifically determined during manufacturing to ensure complete complexation of any free gadolinium ions while complying with the requirements of the United States Pharmacopeia (USP). As described in the manufacturer's clarification letter dated April 2, 2026, Pentetic Acid functions as a chelating agent and is added only in the quantity required to achieve complete chelation of residual free gadolinium ions. The USP monograph for Gadopentetate Dimeglumine

			Injection specifies an acceptable residual Pentetic Acid range of 0.027%–0.040% w/v, and therefore the manufacturing process is designed to maintain the finished product within this pharmacopeial specification rather than incorporating a fixed predetermined quantity of Pentetic Acid. Accordingly, the quantity of Pentetic Acid required for each manufacturing batch is determined using the following calculation: Pentetic Acid (g) = (0.034 − Y) × 10 × Batch Size Where: Y = Measured Pentetic Acid content (mg/mL) in the bulk batch, prior to addition Batch Size = Total manufacturing batch volume, in litres This calculation determines the quantity sufficient (q.s.) of Pentetic Acid required for each batch to achieve complete chelation while avoiding both residual free gadolinium ions and unnecessary excess Pentetic Acid.

Decision

Approved

As per policy for inspection abroad.

793	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	(1NU-NM7-PVEQ, 2025-04-18)
	Detail of Fee Submitted	300000.0, 2025-01-02,
	The proposed proprietary name / brand name	**Gadomine-10ml**
	Label Claim	Each ml Contains: Gadopentetate Dimeglumine 469mg. 4.69g/Unit of 10ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's (10ml Vial)-As per SRO
	Shelf Life (Unit)	36 Year(s)Store at controlled room temperature 20-25°C,excrusion permitted to 15-30°C. Do not freeze. Protect from light and secondary X-ray.
	For generic drugs (me-too Status)	Registration Number: 011539 Brand Name: Magnevist Injection Dosage Form: Injection Registration Date: 2/7/1991 Composition: GADOPENTETATE DIMEGLUMINE 469 MG Market Authorisation Holder: Bayer Pakistan

Pharmacotherapeutic Group of (API)	Gadolinium based contrast agent
Name, address of Manufacturing site:	Unijules Life Sciences Limited-D-82, Cross road no 4 A, MIDC Area, Hingna, Nagpur – 440028 (M.S), India-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE has performed against the comparator Product Gadopentetate Dimeglumine Injection USP 469 mg/ml of M/s. Unique Pharmaceutical Laboratories Batch no. 10023010 Mfg.date: 04-2023
Name, address of Marketing Authorization Holder:	Unijules Life Sciences Limited, D-82, Cross road no 4 A, MIDC Area, Hingna, Nagpur – 440028 (M.S), India, India
Details of Certificates (CoPP/FSC/cGMP):	GMP certificate dated 29th Sep,2022 issued by Food & Drug Administration,Bandra Mumbai.
Details of Authorization Letter :	NA.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm submitted the stability data of drug substance
The status in reference regulatory authorities	MAGNEVIST® (gadopentetate dimeglumine) injection, for intravenous use Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ 07981 Manufactured in Germany UDFDA Approved

Evaluation Remarks

Firm submitted CoPP certificate no. COPP/CERT/ND/147887/2025/11/53997/259699 dated 28th Feb,2025 issued by Food and Drug Administration Bandra, Mumbai valid till 28th Sep,2025. Firm submitted distribution certificate hereby certify that Mis. Lab Diagnostic Systems (SMC)Pvt Ltd Address: Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Punjab as our “PREFERRED" distributor for the territory of Pakistan, M/s. Lab Diagnostic Systems (SMC) Pvt Ltd is also authorized to sell and participate on behalf of Unijules, in government, semi government and other local tenders and sign sale contracts pertaining to the aforesaid tenders and also allowed to distribute products in their brand name: GADOMINE (Gadopentetate Dimeglumine Injection USP 469 mg/ml) in pack sizes of 10ml, 15ml and 20ml glass vials in the territory of Pakistan.

Sr.no.	Observations	Response of the Firm
1.	The innovator product specifies a fixed, pre-determined quantity of diethylenetriamine pentaacetic acid. In contrast, your formulation describes this excipient as “q.s.”, with a calculation formula provided in the manufacturing procedure to determine the required quantity at the time of production. Kindly clarify this difference from innovator. Furthermore, it is noted that the same calculation formula was not applied for determining the quantity during the manufacturing of stability batches, as per the submitted Batch Manufacturing Records (BMRs). Please justify the rationale for not adopting the same method.	In summary, Pentetic Acid is used as a chelating agent to bind free gadolinium ions and ensure product safety. As per USP, it is permitted within a range of 0.027%–0.04%, hence a fixed quantity is not mandatory. A target value of 0.034% (midpoint of the USP range) is used, and the required quantity is calculated based on batch size and existing content to ensure complete chelation without excess. This approach aligns with USP requirements and focuses on controlling free gadolinium levels rather than maintaining a fixed excipient concentration.

Registration Board in its 357th meeting has decided to defer the application for submission of following: Submit valid and legalized Sole Agency Agreement/letter of Authorization pertaining to the instant applied product. Submit evidence of the reference product approved by relevant regulatory authorities/agencies that does not use a fixed, pre-determined quantity of pentetic acid in

its formulation. Instead, the required amount is calculated based on batch size and an amount sufficient to achieve full chelation and to minimize the presence of free gadolinium ions.

Sr.no.	Decision of Registration Board	Response of the Firm
1.	Submit valid and legalized Sole Agency Agreement/letter of Authorization pertaining to the instant applied product.	Firm submitted valid Legalized Letter of Authorization for Gadomine 10ml & 15ml glass vials which is valid until December,2026.
2.	Submit evidence of the reference product approved by relevant regulatory authorities/agencies that does not use a fixed, pre-determined quantity of pentetic acid in its formulation. Instead, the required amount is calculated based on batch size and an amount sufficient to achieve full chelation and to minimize the presence of free gadolinium ions.	The applicant respectfully submits that the quantity of Pentetic Acid incorporated in the manufacture of Gadopentetate Dimeglumine Injection USP 469 mg/mL is not intended to be a fixed formulation quantity, but is scientifically determined during manufacturing to ensure complete complexation of any free gadolinium ions while complying with the requirements of the United States Pharmacopeia (USP). As described in the manufacturer's clarification letter dated April 2, 2026, Pentetic Acid functions as a chelating agent and is added only in the quantity required to achieve complete chelation of residual free gadolinium ions. The USP monograph for Gadopentetate Dimeglumine Injection specifies an acceptable residual Pentetic Acid range of 0.027%–0.040% w/v, and therefore the manufacturing process is designed to maintain the finished product within this pharmacopeial specification rather than incorporating a fixed predetermined quantity of Pentetic Acid. Accordingly, the quantity of Pentetic Acid required for each manufacturing batch is determined using the following calculation: Pentetic Acid (g) = (0.034 − Y) × 10 × Batch Size Where: Y = Measured Pentetic Acid content (mg/mL) in the bulk batch, prior to addition Batch Size = Total manufacturing batch volume, in litres This calculation determines the quantity sufficient (q.s.) of Pentetic Acid required for each batch to achieve complete chelation while avoiding both residual free

			gadolinium ions and unnecessary excess Pentetic Acid.

	Decision
	Approved As per policy for inspection abroad.

794	Case Category	Contract Manufacturing (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	(4ZN-TMH-GHAS, 2024-06-11)
	Detail of Fee Submitted	75000.0, 2024-03-27,
	The proposed proprietary name / brand name	**Criso Ointment 2.0% w/w**
	Label Claim	Each gram of ointment contains Crisaborole.....20mg (2% w/w) (Innovator Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 MonthStore at 20 - 25 °C; excursions permitted to 15 - 30 °C. Keep tube tightly closed.
	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-
	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 US FDA EUCRISA (crisaborole) ointment, for topical use.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Registration Board in its 340th meeting approved the product CRISOLE 2% Ointment on Form-5F in the name of M/s. Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved Firm shall submit fee for pre-registration variation as the latest fee SRO prior the issuance of Registration Letter.	
795	Case Category	Routine (Saima Hussain)
	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	(XBE-RT5-78U5, 2025-05-12)
	Detail of Fee Submitted	37000.0, 2025-04-09,
	The proposed proprietary name / brand name	**Ebak 5mg/5ml Syrup**
	Label Claim	Each 5ml Contains: Ebastine.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml-De-Controlled,60ml-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Kestine 5mg/5ml Liquid By Highnoon Laboratories
	Pharmacotherapeutic Group of (API)	Second-generation H1-antihistamine
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Bal Pharma India Pvt Ltd
	Detail of stability batches of drug product	For 30ml: EMBPD01-30/24, EMBPD02-30/24 &EMBPD03-30/24 For 60ml:EMBPD01/24, EMBPD02/24 & EMBPD03/24
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate issued on 21-Nov-2023 of Batch#5017072310026
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence performed against Kestine liquid by Highnoon Laboratories (Batch#240877)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Real time at Zone IVA stability studies for 60 months & Acc time of three batches (EBS5100107, EBS5100207 & EBS5100307)-Enclosed in Section 3.2.S.7.3 of Module 3
	The status in reference regulatory authorities	Ebastel 1mg/1ml Oral Solution (Approved In CIMA-Spain)
	GMP status of the firm	Valid till 26th-Feb-2028
	Evidence of approval of manufacturing facility	Frim has been granted the section of Liquid (General) on 05-07-2006
	Evaluation Remarks	
	Decision	
	Approved	
796	Case Category	New Section (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	(J5P-GGR-6RHQ, 2026-04-30)
	Detail of Fee Submitted	38700, 2025-12-19,
	The proposed proprietary name / brand name	**Xylotec 2% Jelly**

Label Claim	Each gm of jelly contains: Lidocaine HCl ..... 20mg (USP Specification)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	15gm-Controlled
Shelf Life (Unit)	2 YearStore below 30 degree centigrade
For generic drugs (me-too Status)	Xyloaid Jelly 2% (Manufacturer: Barrett Hodgson Pakistan (Pvt.) Ltd.)
Pharmacotherapeutic Group of (API)	Pharmacotherapeutic group: Local anesthetics, amides ATC code: N01BB02
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	N/A
Detail of stability batches of drug product	Attached in Module 3 sub section 3.2.P.8.3
Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in stability annexures
Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP not applicable, PE attached in Module 3.2.P.2
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Module 3 sub section 3.2.S.7.3
The status in reference regulatory authorities	Lidocaine Hydrochloride Jelly USP, 2% (USFDA Approved)
GMP status of the firm	Attached in Module 1
Evidence of approval of manufacturing facility	Attached in Module 1 Sub-section 1.3.5

Evaluation Remarks

Sr.no.	Observations	Response of the Firm
1.	justification is required for not including the sterility test in the finished product specification. Based on the submitted stability data, only a microbiological examination test has been included, which is applicable to non-sterile preparations. However, the applied formulation is a sterile preparation, and sterility testing is a mandatory requirement as per the United States Pharmacopeia / British Pharmacopoeia monographs.	Firm replied that, the submitted stability data were generated from laboratory-scale development batches used for formulation development and registration purposes. Terminal sterility testing was not included in the development stability protocol; therefore, sterility data are not available for these batches. For commercial manufacturing, sterility testing will be included as a mandatory release requirement in accordance with USP <71> and BP requirements. Additionally, terminal sterility testing will be incorporated into the stability program for commercial-scale batches, where applicable. In view of the above, we respectfully request acceptance of the submitted stability data generated from development batches.
2.	Clarify the sterilization procedure adopted for the Lidocaine Jelly filled in aluminum tubes. Specifically, state whether the finished product is subjected to terminal sterilization or manufactured and filled under aseptic conditions. If terminal sterilization will be done then provide complete details of the sterilization method which can be used without adversely affecting the quality, safety, efficacy, or container-closure integrity of the product. Furthermore, submit supporting	Firm replied that, Lidocaine Jelly filled in aluminum tubes was manufactured at trial stage under a controlled process without terminal sterilization. The product was processed and filled to ensure product physical & analytical quality during development studies. The trial batches were manufactured during the development phase for formulation optimization and process understanding. At that stage, the commercial manufacturing process, including terminal sterilization, was not finalized. The

	documentary evidence from recognized international standards, pharmacopeias, and/or regulatory guidelines (e.g., EU GMP Annex 1, WHO GMP Guidelines, USP, BP, or relevant ICH guidance) justifying the suitability of the selected sterilization approach for Lidocaine Jelly packaged in aluminum tubes. Furthermore, provide a scientific justification for not adopting the same manufacturing process for the trial batches as that intended for the commercial-scale batches. Additionally, provide references to relevant international regulatory guidelines that permit the manufacture of trial batches using a different process compared to the proposed commercial manufacturing process.	commercial process is currently under development and will include terminal sterilization as a final step after sealing of aluminum tubes. This process is subject to completion of validation activities prior to routine commercial manufacturing. It was decided that for commercial manufacturing, terminal sterilization to be introduced for the filled and sealed aluminum tubes. However, the terminal sterilization cycle is currently under development and has not yet been fully validated. The process will only be implemented after successful validation demonstrating achievement of required sterility assurance level without impacting product quality, stability, or container-closure integrity. For this purpose, we will conduct another trial to develop terminal sterilization cycle in autoclave at 121˚C for 30 minutes.

Registration Board in its 360th meeting decided as under: Firm shall submit evidence of approval of the sterile cream/ointment/gel manufacturing facility, issued by the Licensing Division.' Firm in their response informed that Lidocaine/Lignocaine Jelly/Gel 2% formulations were approved by the Registration Board under the Cream/Ointment/Gel (General) or Semi-Solid Manufacturing Section, rather than a specifically designated Sterile Cream/Ointment/Gel Section. The details of the relevant cases are provided below:

S #	Company Name	CLB / RB Meeting	Status	Approved Section / Facility
1	Hamaz Pharmaceuticals (Pvt.) Ltd.	321 RB Meeting Dated: 20–22 Sep, 2022	Approved	Cream/Ointment/Gel (General) Section – Evidence attached
2	Nabiqasim Industries (Pvt.) Ltd.	320 RB Meeting Dated: 29 – 31 Aug, 2022	Approved	Semi-Solid Manufacturing Area for Cream, Ointment and Gel – Evidence attached
3	Eros Pharma (Pvt.) Ltd.	324 RB Meeting Dated: 24 – 26 Jan, 2023	Approved	298th CLB Meeting - Evidence attached
4	Health Care Pharmaceuticals	295 RB Meeting Dated: 8 - 11 Jun, 2020	Approved	270th CLB (2 sections for semi-solid) Meeting - Evidence attached

Firm request the Board to consider their case on the same basis and approve the proposed product.

Decision

Deferred

Deferred for further deliberation.

797	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Aamster Laboratories** Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad **(000908)**
	Application Form Dy. No / Tracking ID & date of submission	(2EZ-P5R-SVAG, 2026-03-26)
	Detail of Fee Submitted	38700, 2026-03-26,
	The proposed proprietary name / brand name	**VALOSTER ORAL POWDER**

	Label Claim	Each gm powder contains (As Per Innovator Spec.) Tylvalosin tartrate BP..... 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	QUANTA SOL 20% PREMIX (125697) HUANGGANG ANIMAL MEDICINE CHINA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The Panel Recommends renewal of Drug Manufacturing License
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
798	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	(42D-P12-XSMH, 2026-01-08)
	Detail of Fee Submitted	38700, 2026-01-07,
	The proposed proprietary name / brand name	**FLOXATIN 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,150ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,Lit-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30c°
	For generic drugs (me-too Status)	NOR-C MAARSON ORAL LIQUID (071056) Attabak Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
799	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	(6LD-R3Q-QP1B, 2026-01-12)

	Detail of Fee Submitted	38700, 2026-01-07,
	The proposed proprietary name / brand name	**NC Maarson Oral Liquid**
	Label Claim	Each 100ml contains (As Per Innovator Spec.) Norfloxacin BP..... 20g Colistin sulphate BP..... 50MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,150ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,Lit-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30c°
	For generic drugs (me-too Status)	COLINOR ORAL LIQUID (071066) Attabak Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
800	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	(7AH-PWU-D2QJ, 2026-01-08)
	Detail of Fee Submitted	38700, 2026-01-07,
	The proposed proprietary name / brand name	**NOXLIN lIQUID**
	Label Claim	Each 100ml contains (As Per Innovator Spec.) Norfloxacin BP..... 20g Guaifenesin USP..... 20g Aminophylline USP..... 8g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,150ml-De-Controlled,250ml-De-Controlled,500ml -De-Controlled,Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	NOR+AG SOLUTION (058968) BIOGEN Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
801	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	(889-GYY-JYDB, 2026-01-08)
	Detail of Fee Submitted	38700, 2026-01-07,
	The proposed proprietary name / brand name	**Fast-Bro Oral Liquid**
	Label Claim	Each 100ml contains (As Per Innovator Spec.) Norfloxacin BP..... 20g Colistin sulphate BP..... 60MIU Bromhexine HCL 0.5g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,150ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,Lit-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30c°
	For generic drugs (me-too Status)	BRONCONOR ORAL LIQUID (071067) Attabak Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
802	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Vetz Pharmaceutical Pvt Ltd** Plot No. Q-1, Site Kotri, Sindh **(000813)**
	Application Form Dy. No / Tracking ID & date of submission	(Q5B-ZUJ-W4AH, 2026-03-17)
	Detail of Fee Submitted	38700, 2026-02-26,
	The proposed proprietary name / brand name	**Quinovetz 10% Oral Powder**
	Label Claim	Each 1 kg contains: Olaquindox.....100gm (As per Innovator's specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm,500gm, 1 kg, 5kg,10kg,20kg and 25kg-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C in a dark & dry place
	For generic drugs (me-too Status)	Olandox Powder
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
803	Case Category	Routine (Sara Mehreen)

	Name, address of Applicant.	**Vetz Pharmaceutical Pvt Ltd** Plot No. Q-1, Site Kotri, Sindh **(000813)**
	Application Form Dy. No / Tracking ID & date of submission	(T8Y-T6Z-NB6X, 2026-03-18)
	Detail of Fee Submitted	38700, 2026-02-26,
	The proposed proprietary name / brand name	**LC-Mycin 4.4% Water Soluble Powder**
	Label Claim	Each 100g Contains: Lincomycin (as HCl) ..... 4.4gm (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 5kg,10kg, 20kg and 25kg-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C and Protect from light and moisture.
	For generic drugs (me-too Status)	Lincofas-44 Powder (133614)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
804	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	(8UM-45E-365Y, 2026-02-07)
	Detail of Fee Submitted	38700, 2025-11-12,
	The proposed proprietary name / brand name	**Zinbac Powder**
	Label Claim	Each gm contains: Zinc Bacitracin .....100mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50gm, 100gm, 250gm, 500gm, 1kg, 2kg,3kg,5kg-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Bio-ZBC 100mg WSP Reg. # 112172
	Pharmacotherapeutic Group of (API)	
	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	
	Evaluation Remarks	
	Decision	
	Approved	
805	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	(AN2-2GN-QUQY, 2026-02-07)
	Detail of Fee Submitted	38700, 2025-11-12,
	The proposed proprietary name / brand name	**Star-Salino Feed Premix**
	Label Claim	Each 1000 gm contains: Salinomycin Sodium.....60g (Innovaotr'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 YearStore below 30°C.
	For generic drugs (me-too Status)	Bio-Salino 6% Feed Premix Reg. # 016243
	Pharmacotherapeutic Group of (API)	
	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	
	Evaluation Remarks	
	Decision	
	Approved	
806	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	(R1W-4BH-XUY7, 2026-02-07)
	Detail of Fee Submitted	38700, 2025-11-12,
	The proposed proprietary name / brand name	**Saraflox Powder**
	Label Claim	Each gm Contains: Sarafloxacin HCl.....100mg (Innovaotr'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 30°C.
	For generic drugs (me-too Status)	Biosar 10% Water Soluble Powder Reg. # 043552
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
807	Case Category	Routine (Sara Mehreen)

	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	(PPS-ETH-XEEX, 2026-03-14)
	Detail of Fee Submitted	38700, 2026-03-11,
	The proposed proprietary name / brand name	**LEVOXYZONE PLUS ORAL DRENCH**
	Label Claim	Each ml contains: Levamisole HCL BP.....15 mg Oxyclozanide BP.....30 mg Cobalt Sulphate BP.....382mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml, 20ml, 50ml, 100ml, 250ml, 500ml, 1liter, 5liter-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature. Protect from direct sunlight
	For generic drugs (me-too Status)	Nilzan Plus Drech
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	N/A
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
808	Case Category	Routine (Sara Mehreen)
	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	(S26-V2A-HBLY, 2026-03-27)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Nicloshield Oral Powder**
	Label Claim	Each gm contains:- Niclosamide BP.....400mg, Levamisole HCl BP.....100mg , Vitamin A USP.....0.15mg } (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 10gm,50gm,100gm,250gm,500gm, 1000g ,5kg,10kg,20kg,25kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	dew-zk oral powder by mallard pharmaceuticals pvt 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	

809	Case Category	Routine (Sara Mehreen)
	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	(43W-E3Z-66ZE, 2026-01-06)
	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**Strox-34% Injection 100ml**
	Label Claim	Each mL Contains: Nitroxynil.....340mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearDo not Store above 25°C. Protect from heat and light.
	For generic drugs (me-too Status)	Troxy-34% Injection by M/s. Selmore Pharmaceuticals (Pvt.) Ltd., (Reg. No.: 034597)
	Pharmacotherapeutic Group of (API)	
	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	
810	Case Category	Routine (Sara Mehreen)
	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	(86G-42U-NZWY, 2026-01-06)
	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**Tylowan-G Injection 100ml**
	Label Claim	Each mL Contains: Tylosin (as Tartrate) BP.....100mg Gentamicin (as Sulphate) BP.....50mg
	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 heat and light.
	For generic drugs (me-too Status)	Tygent Injection by M/s. Selmore Pharmaceutical (Pvt.) Ltd., (Reg. No.: 049636)
	Pharmacotherapeutic Group of (API)	
	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	
811	Case Category	Routine (Sara Mehreen)

	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	(MR4-1TB-1JPY, 2026-01-06)
	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**Valone Injection 50ml**
	Label Claim	Each mL Contains: Buparvaquone.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25°C. Protect from heat and light.
	For generic drugs (me-too Status)	Bupralex Injection by M/s. Star Laboratories (Pvt.) Ltd., (Reg. No.: 033264)
	Pharmacotherapeutic Group of (API)	
	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	
812	Case Category	Routine (Sara Mehreen)
	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	(QTH-TJ7-B3MY, 2026-01-06)
	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**Valone Injection 100ml**
	Label Claim	Each mL Contains: Buparvaquone.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25°C. Protect from heat and light.
	For generic drugs (me-too Status)	Bupralex Injection by M/s. Star Laboratories (Pvt.) Ltd., (Reg. No.: 033264)
	Pharmacotherapeutic Group of (API)	
	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	
813	Case Category	Routine (Sara Mehreen)
	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	(X78-UYQ-HHWQ, 2026-01-06)
	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**Strox-34% Injection 50ml**
	Label Claim	Each mL Contains: Nitroxynil.....340mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearDo not Store above 25°C. Protect from heat and light.
	For generic drugs (me-too Status)	Redox-34 Injection by M/s. Dmaarson Pharmaceuticals., (Reg. No.: 106624)
	Pharmacotherapeutic Group of (API)	
	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	
814	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(MJD-5WT-ZDWG, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-25,
	The proposed proprietary name / brand name	**Stopper Drench**
	Label Claim	Each 100ml Contains: Triclabendazole BP... 12gm Albendazole BP... 10gm Ivermectin BP... 0.20gm As per Innovator’s Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	De-Controlled-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 25ºC
	For generic drugs (me-too Status)	THUNDER DRENCH of M/s. Star Labs (Reg. No. 058941)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
815	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(NSA-BD9-VNWM, 2026-03-26)

	Detail of Fee Submitted	38700, 2026-03-25,
	The proposed proprietary name / brand name	**AL-FLOR 25% ORAL LIQUID**
	Label Claim	Each ml Contains: Florfenicol ... 250mg As per Innovator's Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml, 450ml, 500ml & 1000ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC
	For generic drugs (me-too Status)	FLORFENICOL ORAL LIQUID M/s. Attabak Pharma (Reg. No. 075707)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
816	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(QUN-2LW-BJN3, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-25,
	The proposed proprietary name / brand name	**CYPERZON SPRAY**
	Label Claim	Each 100 ml Contains: - Cypermethrin ..... 10 gm. (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	De-Controlled-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC
	For generic drugs (me-too Status)	CPM-100 EXTERNAL SPARY of M/s. SANA LABS (Reg. No. 031445)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
817	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(XTH-YH7-T1TR, 2026-03-26)
	Detail of Fee Submitted	38700, 2026-03-25,

	The proposed proprietary name / brand name	**BROCID WSP**
	Label Claim	Each 100 gm Contains: Bromhexine HCl ... 1gram Tartaric Acid .....15gram As per Innovator's Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20gm, 100gm, 500gm, 1000gm, 5Kg, 10Kg, 25Kg, 20Kg & 25Kg-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC
	For generic drugs (me-too Status)	BROMOTARIC WSP of M/s. Lucky Core Industries (Reg. No. 089822)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
818	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	(1VD-4M7-N1N2, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**TOP ROFEN INJECTION**
	Label Claim	Each ml contains: KETOPROFEN USP..... 100mg (As Per Innovator.s Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	KETOVET INJECTION. (102014)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
819	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	(GYU-UPG-2P26, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**TOP ROFEN INJECTION**
	Label Claim	Each ml contains: KETOPROFEN USP..... 100mg (As Per Innovator.s Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	KETOVET INJECTION. (079292)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
820	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	(RY6-Q5M-PZ71, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**TOP ROFEN INJECTION**
	Label Claim	Each ml contains: KETOPROFEN..... 100mg (As Per Innovator.s Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ml-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	KETOVET INJECTION. (088156)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
821	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	(R3W-6T9-ZS1A, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**CYNOPIC- 1000 INJECTION**
	Label Claim	Each ml contains Cyanocobalamine..... 1000µg (USP Spec.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	AMVIT-1000 INJECTION
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
822	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	(23E-DEU-4WGS, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**CYNOPIC- 1000 INJECTION**
	Label Claim	Each ml contains Cyanocobalamine USP..... 1000µg (USP Spec.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	AMVIT-1000 INJECTION Reg. # (109914)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility

		demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
823	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	(43H-76Q-E5T5, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**MELOX- 800 INJECTION**
	Label Claim	Each ml contains Meloxicam BP..... 8mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	CAMROLD 8 LIQUID INJECTION (109000)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
824	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	(Q7U-7BW-QDU9, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**MELOX- 800 INJECTION**
	Label Claim	Each ml contains Meloxicam ..... 8mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	CAMROLD 8 LIQUID INJECTION (109001)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
825	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	(RNY-JLJ-8QEJ, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**MELOX-2000 INJECTION**
	Label Claim	Each ml contains Meloxicam ..... 20mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	CAMROLD 20 LIQUID INJECTION (109005)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
826	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	(Z39-BS2-LDRV, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**MELOX-2000 INJECTION**
	Label Claim	Each ml contains Meloxicam ..... 20mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ML-De-Controlled

	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	CAMROLD 20 LIQUID INJECTION (109006)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
827	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	(47E-A89-LEEM, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**KETO LA INJECTION**
	Label Claim	Each ml contains: Oxytetracycline USP..... 200mg Ketoprofen USP..... 30mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	OXYFEN LA INJECTION (071091)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
828	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	(8QN-YVD-HN98, 2026-02-28)

	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**KETO LA INJECTION**
	Label Claim	Each ml contains: Oxytetracycline USP..... 200mg Ketoprofen USP..... 30mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	OXYFEN LA INJECTION (071091)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
829	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	(RES-18X-R3L4, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**KETO LA INJECTION**
	Label Claim	Each ml contains Oxytetracycline USP..... 200mg Ketoprofen USP..... 30mg (As Per Innovator Spec
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	OXYFEN LA INJECTION (071091)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
830	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	(YXS-54R-8EDU, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**HEXASOL-LA INJECTION**
	Label Claim	EACH 100ML CONTAINS:- Oxytetracycline HCL USP..... 30 gm Flunixin Meglumine USP..... 2.0 gm (As Per Innovator Spec)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	I- FOM INJECTION. (062076)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
831	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	(6PL-Q1Y-3UGL, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**ZINE INJECTION**
	Label Claim	EACH 100ML CONTAINS: - XYLAZINE HCL USP....2GM (As per innovator' S Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	I-XAZINE INJECTION.. (062067)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility

		demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
832	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	(N3Y-8VP-5RYU, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**ZINE INJECTION**
	Label Claim	EACH 100ML CONTAINS: - XYLAZINE HCL USP....2GM (As per innovator' S Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	I-XAZINE INJECTION.. (062067)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
833	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	(D3M-6H1-ZXM8, 2026-02-27)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**VITO-MECTINE INJECTION**
	Label Claim	EACH 100ML CONTAINS: - IVERMECTIN USP....1G VITAMIN A USP....2500,000IU VITAMIN D3 USP....375000IU VITAMIN E USP....2.5G (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	MECTIN PLUS INJECTION (059142)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
834	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	(LRP-JYM-R98M, 2026-02-27)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**VITO-MECTINE INJECTION**
	Label Claim	EACH 100ML CONTAINS: - IVERMECTIN USP....1G VITAMIN A USP....2500,000IU VITAMIN D3 USP....375000IU VITAMIN E USP....2.5G (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	MECTIN PLUS INJECTION (059142)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
835	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	(SNS-MBT-8DTL, 2026-02-27)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**FENICOL 30% INJECTION**

	Label Claim	Each ml contains Florfenicol..... ..... 30mg (As per Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	PREM FENICOL INJECTION (111318)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
836	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	(ZWD-NN4-RJVX, 2026-02-27)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**VITO-MECTINE INJECTION**
	Label Claim	EACH 100ML CONTAINS: - IVERMECTIN USP....1G VITAMIN A USP....2500,000IU VITAMIN D3 USP....375000IU VITAMIN E USP....2.5G (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	MECTIN PLUS INJECTION (059142)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
837	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	(YAJ-2M2-N4L3, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**TYLAN 20 INJECTION**
	Label Claim	Each ml contains: Tylosin Tartrate USP ..... 200mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	TYLOSEL INJECTION. (043534)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
838	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	(XAP-EWW-J7B1, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**TYLAN 20 INJECTION**
	Label Claim	Each ml contains: Tylosin Tartrate USP..... 200mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	TYLOSEL INJECTION. (043534)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
839	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	(Y9S-X43-J8G3, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**SELON E INJECTION**
	Label Claim	Each ml contains Vitamin E USP..... 75mg Sodium Selenite BP.....0.60mg (As Per Innovator Spec)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	Selferol Injection.. (034579)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
840	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	(Y2Q-AS2-JXDR, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**QUINE INJECTION**
	Label Claim	Each ml contains Buparvaquone ..... 50mg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	BUPRALEX INJECTION. (033264)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices

		(GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
841	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	(R4N-G1E-B3PB, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**TONOFOS INJECTION**
	Label Claim	Each ml contains Toldimfos Sodium ..... 200mg Vitamin B12 USP.....50mcg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	Tolivetz-B Injection. (099472)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
842	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	(Q8Y-YNW-NMGY, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**HEXASOL-LA INJECTION**
	Label Claim	EACH 100ML CONTAINS:- Oxytetracycline HCL USP..... 30 gm Flunixin Meglumine BP..... 2.0 gm (As Per Innovator Spec)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled

	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	I- FOM INJECTION. (062076)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
843	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	(P7J-9PB-GEMQ, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**IMIZOLE INJECTION**
	Label Claim	Each ml contains Imidocarb Dipropionate..... 120mg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ml-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	RED MIDO INJECTION . (063715)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
844	Case Category	Routine (Sara Mehreen)
	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	(US2-45P-NW5S, 2026-01-08)
	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**Toldifon Injection 100ML**

	Label Claim	Each ml contains: Toldimfos Soidum.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Yearbelow 30
	For generic drugs (me-too Status)	Metaras Injection (Reg No. 111461)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	based on the stated observation their current GMP compliance level is rated as Good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
845	Case Category	Routine (Sara Mehreen)
	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	(TL2-HD4-ZX3E, 2026-01-08)
	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**Nawacin L.A. Injection 100ML**
	Label Claim	Each ml contains: Oxytetracycline (as HCl) USP.....200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)below 25
	For generic drugs (me-too Status)	Oxy-L.A. Injection (Reg No. 035014)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	based on the stated observation their current GMP compliance level is rated as Good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
846	Case Category	Routine (Sara Mehreen)
	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	(S2Z-UTY-NTEV, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-23,
	The proposed proprietary name / brand name	**Amovet-GT Injection 50ml**
	Label Claim	Each ml contains: Amoxicillin as Trihydrate USP..... 150mg Gentamicin as Sulphate USP..... 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled

	Shelf Life (Unit)	2 Year(s)below 25
	For generic drugs (me-too Status)	Amoxygent Forte IM 50ml Injection (Reg No. 097945)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	based on the stated observation their current GMP compliance level is rated as Good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
847	Case Category	Routine (Sara Mehreen)
	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	(RT5-3ED-JXJR, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-23,
	The proposed proprietary name / brand name	**Trimodin-48 Injection 100ml**
	Label Claim	Each ml Contains: Trimethoprim USP..... 80mg Sulphadiazine USP..... 400mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)below 25
	For generic drugs (me-too Status)	Tribrissen Injection 48% (Reg No. 091891)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	based on the stated observation their current GMP compliance level is rated as Good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
848	Case Category	Routine (Sara Mehreen)
	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	(2M6-5D8-TL84, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**Broxine 0.5 W/S Powder**
	Label Claim	Each 100 gm contains Bromhexine HCl.....0.5 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000g-De-Controlled,100g-De-Controlled,150g-De-Controlled,250g-De-Controlled,500g-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30c°

	For generic drugs (me-too Status)	COFSTER-5 ORAL WATER SOLUBLE POWDER (101494) AAMSTER LABORATORIESRAWAT, ISLAMABAD.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for grant of drug manufacturing licence(by way of formulation)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
849	Case Category	Routine (Sara Mehreen)
	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	(6AH-Q51-HP13, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**SAL-VIR-98 Powder**
	Label Claim	Each 100 gm contains Amantadine HCL BP.....98 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000g-De-Controlled,100g-De-Controlled,150g-De-Controlled,250g-De-Controlled,500g-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	AMSTERDINE-98 ORAL WATER SOLUBLE POWDER (101995) AAMSTER LABORATORIESRAWAT, ISLAMABAD.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for grant of drug manufacturing licence(by way of formulation)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has mentioned Recommended Dosage in Dogs & Cats. Approved pack size is 100g only.	
	Decision	
	Approved	
850	Case Category	Routine (Sara Mehreen)
	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	(J3P-GBT-ZD31, 2026-01-01)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**FORD-MAX 25% W/S POWDER**
	Label Claim	Each Gm contains (USP Spec.) Chlortetracycline as Hcl 250mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100g-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled,Kg-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	MERALIN 250 W/S POWDER (101462) MY LABS PHARMA
	Pharmacotherapeutic Group of (API)	
	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	
851	Case Category	Routine (Sara Mehreen)
	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	(T5N-VBJ-TBMN, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**DE-VEC 0.8 Oral Drench**
	Label Claim	Each ml Contains; Ivermectin.....0.8 mg (As per USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,150ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30c°
	For generic drugs (me-too Status)	MEC-FORD DRENCH (Reg. No. 018681-EX) M/S SALFORD LABORATORIES BHIMBER, A.J&KASHMIR
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for grant of drug manufacturing licence(by way of formulation)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
852	Case Category	Routine (Sara Mehreen)
	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	(WTB-TE5-H2V6, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**ENGUA-A Oral Liquid**

	Label Claim	Each ml Contains; Enrofloxacin.....100 mg, Guaiphenesin BP.....100 mg Aminophylline BP.....40 mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000g-De-Controlled,100g-De-Controlled,150g-De-Controlled,250g-De-Controlled,500g-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	AG-Flox Oral Liquid (Reg. No. 117034) M/S ACME PHARMACEUTICALS RAWAT, ISLAMABAD
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for grant of drug manufacturing licence(by way of formulation)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
853	Case Category	Routine (Sara Mehreen)
	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	(X77-5LV-9GRZ, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**SAL-C 100% W/S Powder**
	Label Claim	Each 100 gm contains Vitamin C BP.....100 gm (BP)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1000g-De-Controlled,100g-De-Controlled,150g-De-Controlled,250g-De-Controlled,500g-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30c°
	For generic drugs (me-too Status)	ASCOR-C 100% ORAL WATER SOLUBLE POWDER (014036-EX) AAMSTER LABORATORIESRAWAT, ISLAMABAD.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for grant of drug manufacturing licence(by way of formulation)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
854	Case Category	Routine (Sara Mehreen)
	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	(XY8-946-UHXG, 2026-01-01)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**FORD-MAX 20% W/S POWDER**
	Label Claim	Each 100gm contains (USP Spec.) Chlortetracycline HCl 20g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100g-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled,Kg-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	CT MORE W/S POWDER (089851) MORENO IGLISIAS RESEARCH LABORATORIES
	Pharmacotherapeutic Group of (API)	
	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	
855	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)**
	Application Form Dy. No / Tracking ID & date of submission	(PT6-XHX-TVQ8, 2026-01-09)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	**Meloxin 20**
	Label Claim	Each ml contains Meloxicam BP.....20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Less Than 25C
	For generic drugs (me-too Status)	Metrym Injection, Nawan Laboratories, Reg. # 044961
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML Renewal
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
856	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(XWL-G85-Q42H, 2026-01-09)
	Detail of Fee Submitted	38700, 2026-01-08,

	The proposed proprietary name / brand name	**SPIRAFAS-L INJECTION**
	Label Claim	Each ml Contains: SPIRAMYCIN ADIPATE BP.....125MG LINCOMYCIN AS HCL BP.....75MG (AS PER INNOVATOR'S SPECIFICATIONS)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) 30 degree centigrade
	For generic drugs (me-too Status)	Aplira Injection (Reg no. 122344) Aptly Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhupura Road, Sheikhupura 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	
857	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(W88-JYP-872Y, 2026-01-09)
	Detail of Fee Submitted	38700, 2026-01-08,
	The proposed proprietary name / brand name	**SPIRAFAS-L INJECTION**
	Label Claim	Each ml Contains: SPIRAMYCIN ADIPATE BP.....125MG LINCOMYCIN AS HCL BP.....75MG (AS PER INNOVATOR'S SPECIFICATIONS)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) 30 degree centigrade
	For generic drugs (me-too Status)	Aplira Injection (Reg no. 122345) Aptly Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhupura Road, Sheikhupura 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	
858	Case Category	Routine (Sara Mehreen)
	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	(SWW-HSU-AXXP, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-09,
	The proposed proprietary name / brand name	**Tiaklor Oral Powder**
	Label Claim	Each 100 gram powder contains Tiamuline (as Hydrogen Fumerate) USP ..... 10 g Chlortetracycline (as HCl) BP ..... 30 g (As per Innovator's Specifications).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30g, 50g,100g, 250g, 500g, 1000g, 5000g, 10,000g, 25,000g-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store at controlled room temperature.
	For generic drugs (me-too Status)	Tiagence Water Soluble Powder Reg. No. 103968
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Yes
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
859	Case Category	Routine (Sara Mehreen)
	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	(9LH-Z3T-Z4V8, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-09,
	The proposed proprietary name / brand name	**Vita E-Sel 50 mL Injection**
	Label Claim	Each mL contains Vitamin E USP..... 100 mg Selenium USP..... 0.5 mg (As per Innovator’s specifications).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 mL-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store at controlled room temperature below 25 degree centigrade
	For generic drugs (me-too Status)	V Sel Injection Reg. No. 088141
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Yes
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

860	Case Category	Routine (Sara Mehreen)
	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	(EQA-358-SGYZ, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-09,
	The proposed proprietary name / brand name	**ESEL 100 mL injection**
	Label Claim	Each mL contains Vitamin E USP..... 100 mg Selenium USP..... 0.5 mg (As per Innovator's specifications).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 mL-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store at controlled room temperature below 25 centigrade degree
	For generic drugs (me-too Status)	V Sel Injection Reg. No. 088141
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Yes
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
861	Case Category	Import (Sara Mehreen)
	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	(E8H-PS6-ZR5W, 2026-01-29)
	Detail of Fee Submitted	313500, 2026-01-17,
	The proposed proprietary name / brand name	**CENTRE-AMOXY LA 15%**
	Label Claim	Each 1 ml contains 150 mg of Amoxicillin Trihydrate BP
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C at a cool, dry place and avoid light
	For generic drugs (me-too Status)	Alfamox LA 150 mg/ml suspension
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Aether Centre Biology Co., Ltd-No.158,Jingang Dadao,New District,Zhenjiang City China-China
	Name, address of Marketing Authorization Holder:	Aether Centre Biology Co., Ltd, No.158,Jingang Dadao,New District,Zhenjiang City China, China
	Details of Certificates (CoPP/FSC/cGMP):	Firm has provided copy of GMP certificate.
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Decision	

	Approved	
862	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	(AUB-RAV-MVTZ, 2026-03-27)
	Detail of Fee Submitted	38700, 2026-03-26,
	The proposed proprietary name / brand name	**Talonex WSP**
	Label Claim	Each kg contains Tiamulin hydrogen fumarate BP .....124gm Chlortetracycline Hydrochloride B.P.....321.54gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1-De-Controlled,500-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at Room Temperature
	For generic drugs (me-too Status)	TIAMULIN-CT ORAL POWDER 111369 by M/S. KAYANS PHARMACEUTICALS, PLOT NO. 31,32 MAIN ROAD RCCI INDUSTRIAL ESTATE, RAWAT, RAWALPINDI.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	PASS
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
863	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	(YUB-HYY-UU69, 2026-03-27)
	Detail of Fee Submitted	38700, 2026-03-26,
	The proposed proprietary name / brand name	**Diarex Oral Suspension**
	Label Claim	Each 100ml contains: Sulphadiazine USP.....3.550gm, Sulphadimidine BP..... 2.840gm, Neomycin Sulphate USP .....0.180gm, Hyoscine Methylbromide BP..... 0.004gm, Pectin USP ..... 0.710gm, Kaolin USP ..... 10.330gm, Vitamin B1 USP ..... 0.015gm, Vitamin B2 USP 0.022gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000-De-Controlled,25-De-Controlled,5-De-Controlled,500-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature
	For generic drugs (me-too Status)	Scour X oral suspension by M/s Selmore Pharmaceuticals
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	--
	GMP status of the firm	PASS
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
864	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	(YYH-6WT-6TJ1, 2026-03-26)
	Detail of Fee Submitted	38700, 2026-03-26,
	The proposed proprietary name / brand name	**Trivezole Drench**
	Label Claim	Each 100mL contains:- Triclabendazole USP.....12gm Ivermectin USP.....0.2gm Albendazole BP.....10gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ML-De-Controlled,200ML-De-Controlled,250ML-De-Controlled,50-De-Controlled,500ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)sTORE ATR ROOM TEMPERATURE
	For generic drugs (me-too Status)	THUNDER DRENCH (058941) by M/S STAR LABS
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	PASS
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
865	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(ZL9-PLE-566Z, 2026-03-26)
	Detail of Fee Submitted	38700, 2026-03-25,
	The proposed proprietary name / brand name	**NORCOT SOLUTION**
	Label Claim	Each 100ml Contains: Norfloxacin ... 10g Tylosin Tartrate ... 5g Colistin Sulphate ... 250MIU As per Innovator’s Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 25ºC
	For generic drugs (me-too Status)	NORCOTYL ORAL SOLUTION M/s. BioGen Pharma (Reg. No. 071021)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
866	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	(4JJ-7HD-BW9J, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**SELON E INJECTION**
	Label Claim	Each ml contains Vitamin E ..... 75mg Sodium Selenite .....0.60mg (As Per Innovator Spec)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	Selferol Injection.. (034579)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
867	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	(6Y4-VML-E7H4, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**RENA DINE INJECTION**
	Label Claim	Each ml contains: FUROSEMIDE USP..... 50mg (USP Specs.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	DURETIC INJECTION. (078208)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
868	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	(HA2-7EV-6VED, 2026-02-27)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**MELOX-1000 INJECTION**
	Label Claim	Each ml contains Meloxicam BP ..... 10mg (BP Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	LOXIBAK 10% INJECTION. (062155)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
869	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	(A3J-PRR-XH7M, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**TYLAN 20 INJECTION**
	Label Claim	Each ml contains: Tylosin Tartrate USP..... 200mg (As Per Innovator

		Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	TYLOSEL INJECTION. (043534)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
870	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	(BEM-9LY-RU5R, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**HEXASOL-LA INJECTION**
	Label Claim	EACH 100ML CONTAINS:- Oxytetracycline HCL USP..... 30 gm Flunixin Meglumine USP..... 2.0 gm (As Per Innovator Spec)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	I- FOM INJECTION. (062076)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
871	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	(DHD-89Q-EWLT, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**ZINE INJECTION**
	Label Claim	EACH 100ML CONTAINS: - XYLAZINE HCL USP....2GM (As per innovator' S Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	I-XAZINE INJECTION.. (062067)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
872	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	(GY9-WXS-2TT7, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**THRUSH- CRD INJECTION**
	Label Claim	Each ml contains:- Tylosin Tartrate USP.....100mg Colistin Sulphate BP.....20mg Streptomycin Sulphate USP...200mg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	CRD Plus Injection. (073934)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
873	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	(HBE-JRB-X2QD, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**QUINE INJECTION**
	Label Claim	Each ml contains Buparvaquone ..... 50mg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	BUPRALEX INJECTION. (033264)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
874	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	(HMB-E19-RMSW, 2026-02-27)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**FENICOL 30% INJECTION**
	Label Claim	Each ml contains Florfenicol..... ..... 30mg (As per Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ml-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	PREM FENICOL INJECTION (111316)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility

		demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
875	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	(LVJ-42A-RXNZ, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**SELON E INJECTION**
	Label Claim	Each ml contains Vitamin E USP..... 75mg Sodium Selenite EU.....0.60mg (As Per Innovator Spec)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	Selferol Injection.. (034579)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
876	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	(LXD-RA3-A4LY, 2026-02-27)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**FENICOL 30% INJECTION**
	Label Claim	Each ml contains Florfenicol..... ..... 30mg (As per Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	PREM FENICOL INJECTION (111317)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
877	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	(M4V-E2E-JTVU, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**IMIZOLE INJECTION**
	Label Claim	Each ml contains Imidocarb Dipropionate ..... 120mg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	RED MIDO INJECTION . (063715)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
878	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	(MH6-3WH-XYGG, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**RENA DINE INJECTION**

	Label Claim	Each ml contains: FUROSEMIDE USP..... 50mg (USP Specs.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	DURETIC INJECTION. (078208)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
879	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(4R6-4D1-4X8Z, 2026-03-25)
	Detail of Fee Submitted	38700, 2026-02-25,
	The proposed proprietary name / brand name	**IVER-LIGHT INJECTION**
	Label Claim	Each ml contains: - Ivermectin ... 10mg Clorsulon ... 100mg USP Specification
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC
	For generic drugs (me-too Status)	CLORTIN INJECTION of M/s Univet Pharma (Reg. No. 113570)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
880	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(B2X-7E4-725X, 2026-03-25)
	Detail of Fee Submitted	38700, 2026-02-25,
	The proposed proprietary name / brand name	**IVER-LIGHT INJECTION**

	Label Claim	Each ml contains: - Ivermectin ... 10mg Clorsulon ... 100mg USP Specification
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC
	For generic drugs (me-too Status)	CLORTIN INJECTION of M/s Univet Pharma (Reg. No. 113567)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
881	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(5RS-2H5-MG6W, 2026-03-25)
	Detail of Fee Submitted	38700, 2026-02-25,
	The proposed proprietary name / brand name	**MECO-LIGHT INJECTION**
	Label Claim	Each ml contains: - Ivermectin ... 10.20mg BP Vet Specification
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC
	For generic drugs (me-too Status)	ETO-IVER 10.20 INJECTION of M/s. Eterna Pharma (Reg. No. 122545, 109831)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
882	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(911-9GS-1V2W, 2026-03-25)
	Detail of Fee Submitted	38700, 2026-02-25,
	The proposed proprietary name / brand name	**MECO-LIGHT INJECTION**
	Label Claim	Each ml contains: - Ivermectin ... 10.20mg BP Vet Specification
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC
	For generic drugs (me-too Status)	ETO-IVER 10.20 INJECTION of M/s. Eterna Pharma (Reg. No. 122545, 109831)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
883	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(B34-SSM-NVDZ, 2026-03-25)
	Detail of Fee Submitted	38700, 2026-02-25,
	The proposed proprietary name / brand name	**MECO-LIGHT INJECTION**
	Label Claim	Each ml contains: - Ivermectin ... 10.20mg BP Vet Specification
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC
	For generic drugs (me-too Status)	ETO-IVER 10.20 INJECTION of M/s. Eterna Pharma (Reg. No. 122545, 109831)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
884	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(UHQ-7X4-9BMZ, 2026-03-25)
	Detail of Fee Submitted	38700, 2026-02-25,
	The proposed proprietary name / brand name	**IVER-LIGHT INJECTION**
	Label Claim	Each ml contains: - Ivermectin ... 10mg Clorsulon ... 100mg USP Specification
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC

	For generic drugs (me-too Status)	CLORTIN INJECTION of M/s Univet Pharma (Reg. No. 113569)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
885	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(H6T-295-LTHR, 2026-03-24)
	Detail of Fee Submitted	38700, 2026-03-09,
	The proposed proprietary name / brand name	**MEPRAZON INJECTION**
	Label Claim	Each ml contains: - Mepyramine maleate ... 50mg As per B.P Specification
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC
	For generic drugs (me-too Status)	i. I-MEPA INJECTION of M/s. IPL LAHORE. (Reg. No. 048206) ii. ALLERGINIL INJECTION of M/s. Sanna Labortories (Reg. No. 069623)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
886	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(MPD-T5E-N93L, 2026-03-26)
	Detail of Fee Submitted	38700, 2026-03-25,
	The proposed proprietary name / brand name	**NEOCIZON 70% WSP**
	Label Claim	Each 100gm Contains: Neomycin Sulphate ... 70gm As per Innovator’s Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20gm, 100gm, 500gm, 1000gm-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC
	For generic drugs (me-too Status)	Neomycin 70% Powder of M/s. Attabak Pharma (Reg. No. 075694)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
887	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(NNE-SAZ-HX4G, 2026-03-16)
	Detail of Fee Submitted	38700, 2026-03-12,
	The proposed proprietary name / brand name	**Oxyflox Injection**
	Label Claim	Each ml contains: - DL-Acetyl Methionine ... 200mg Cyanocobalamin ... 0.2mg L-Carnitine hydrochloride ... 61.3mg (e.q to L Carnitine 50mg) Alpha-Tocopherol Acetate 32.9mg (eq. to alpha tocopherol 30mg) (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC
	For generic drugs (me-too Status)	Sterivit INJECTION of M/s. Selmore Pharma. (Reg. No 095650)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
888	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(WY5-G3D-D63D, 2026-03-25)
	Detail of Fee Submitted	38700, 2026-02-25,
	The proposed proprietary name / brand name	**ADE-LIGHT INJECTION**
	Label Claim	Each ml contains: - Vitamin A (Retinyl Palmitate) ... 80,000 IU Vitamin D3 (Cholecalciferol) ... 40,000IU Vitamin E (dl-u-tocopherol acetate) ... 20mg As per Innovators Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC

	For generic drugs (me-too Status)	3-VITZ INJECTION of M/s Epoch Pharma (Reg. No. 069614)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
889	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	(99E-X9Q-5EL9, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-26,
	The proposed proprietary name / brand name	**NORTRIM ORAL LIQUID**
	Label Claim	Each 100 ml contains NORFLOXACIN (Ph.Eur) .....10gm SULFAMETHOXYPYRIDAZINE (BP)...15gm TRIMETHOPRIM (BP).....3gm Product complies with innovator's specs.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled,1000 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)below 25 degree
	For generic drugs (me-too Status)	Approved
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and the review of the production facilities, building, equipment, quality control and quality assurance, the
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
890	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	(DQA-G52-J5DZ, 2026-02-27)
	Detail of Fee Submitted	38700, 2026-02-26,
	The proposed proprietary name / brand name	**DairyGrow POWDER**
	Label Claim	Each Kg Contains: VITAMIN A (BP)--------- -0.8gm VITAMIN D3 (BP)----------0.16gm

		VITAMIN E (BP)----------0.38gm VITAMIN B1 (BP)----------1.0gm VITAMIN B2 (BP)---------- -1.25gm VITAMIN B12 (BP)----------0.001gm VITAMIN B3 (BP)----------6.25gm COPPER SULPHATE (BP)---------- 0.25gm MAGNESIUM SULPHATE (BP)----------25gm CALCIUM CHLORIDE (BP)----------0.023gm ZINC SULPHATE (BP) ----------2.17gm MANGANESE SULPHATE (BP)---------- -10.00gm POTASSIUM IODIDE (BP)---------- -0.5gm SODIUM SELENITE (BP)---------- -0.01gm D.C.P (PHOSPHORUS) (BP)---------- -150gm SODIUM CHLORIDE (BP) ---------- -120gm VITAMIN B6 (BP)----------4.00gm (Product complies with innovator's specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,25 Kg-De-Controlled,5 Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)below 25 degree
	For generic drugs (me-too Status)	Approved
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and the review of the production facilities, building, equipment, quality control and quality assurance, the
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
891	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	(MVL-A17-46AR, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-02-03,
	The proposed proprietary name / brand name	**NORPHEN ORAL LIQUID**
	Label Claim	Each 100 ml contains NORFLOXACIN(Ph.Eur).....20gm AMINOPHYLLIN (BP).... .....8gm GUAIPHENESIN (BP).....20gm Product complies with innovator's specs.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled,1000 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)below 25 degree
	For generic drugs (me-too Status)	Approved
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and the review of the production facilities, building, equipment, quality control and quality assurance, the
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
892	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Biogen Pharma** 8-KM, Chak Beli Road, Rawat, **(000639)**
	Application Form Dy. No / Tracking ID & date of submission	(MX9-D5V-7JUL, 2026-02-18)
	Detail of Fee Submitted	38700, 2026-01-13,
	The proposed proprietary name / brand name	**MACTOGEN-E INJECTION 10ml**
	Label Claim	Each ml contains: - Ivermectin.....10mg Vitamin E.....5mg (Innovator‟s Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 YearRoom Condition
	For generic drugs (me-too Status)	Vetz-Mec Injection
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
893	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Biogen Pharma** 8-KM, Chak Beli Road, Rawat, **(000639)**
	Application Form Dy. No / Tracking ID & date of submission	(PH2-MZW-UVR8, 2026-02-18)
	Detail of Fee Submitted	38700, 2026-01-13,
	The proposed proprietary name / brand name	**MACTOGEN-E INJECTION 100ml**
	Label Claim	Each ml contains: - Ivermectin.....10mg Vitamin E.....5mg (Innovator’s Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearRoom Condition
	For generic drugs (me-too Status)	MACTOGEN-E INJECTION 100ml
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Approved
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
894	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Bioskils Pharmaceuticals** 4-km Tambly, GT road, Sadhoke, District Gujranwala **(000930)**
	Application Form Dy. No / Tracking ID & date of submission	(ZQ6-95B-MGN2, 2026-03-16)
	Detail of Fee Submitted	38700, 2026-03-14,
	The proposed proprietary name / brand name	**Amproskill-60 Oral Powder**
	Label Claim	Each 100 gram contains: Amprolium HCl..... 60 gram
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100gm-De-Controlled,1kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,2kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 YearStore at Room Temperature
	For generic drugs (me-too Status)	Bio-Amprol 60 Powder (Reg. No. 063773) by Mallard Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
895	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	(5J9-T9S-62Z4, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2025-01-10,
	The proposed proprietary name / brand name	**GENCOTYL INJECTION (50ML)**
	Label Claim	Each 100ml contains: Gentamycin Sulphate BP..... 5gm Tylosin tartrae BP..... 10gm Colistin Sulphate BP..... 50MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	GENTAFATE INJECTION REG. # 099348 (INSHAL PHARMACEUTICAL INDUSTRIES ISLAMABAD)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
896	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(8ZT-3VG-DBBX, 2026-03-25)
	Detail of Fee Submitted	38700, 2026-01-07,
	The proposed proprietary name / brand name	**Fagocin 5% Injection 50ml**
	Label Claim	Each ml. contains: - Enrofloxacin..... 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearStore at cool and dry place. • Store at room temperature (25□C - 30□C) • Protect from direct sun light and heat.
	For generic drugs (me-too Status)	Bio-E-Floxacin 5% Injection (Reg. # 088835) 14. Name of company manufacturing in Pakistan. Bio-Labs (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Inspection was conducted on 23rd of December 2025 (Report copy Attached) Remarks of the Panels are as follows:- Based on the documentation reveiwed, technical/management people met, material/processes flow and detailed inspection of the stores, section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
897	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(MV9-JMG-LX7M, 2026-03-24)
	Detail of Fee Submitted	38700, 2025-10-14,
	The proposed proprietary name / brand name	**LEVAXON-75 POWDER**
	Label Claim	Each 100gm. contains Levamisole HCL BP.....75gm (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Kg-De-Controlled,1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,20gm-De-Controlled,25Kg-De-Controlled,5 Kg-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. • Store at room temperature (25□C - 30□C) • Protect from direct sun light and heat.

	For generic drugs (me-too Status)	LIMUSOL SE-75% Powder (Reg. No. 099058) 12. Name of company manufacturing in Pakistan. VETEC LABORATORIES RAWAT
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Inspection was conducted on 23rd of December 2025 (Report copy Attached) Remarks of the Panels are as follows:- Based on the documentation reveiwed, technical/management people met, material/processes flow and detailed inspection of the stores, section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
898	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(MVH-VH1-D2GP, 2026-03-24)
	Detail of Fee Submitted	38700, 2026-01-07,
	The proposed proprietary name / brand name	**TRIXON POWDER**
	Label Claim	Each 100gm. contains Doxycycline Hcl.....20g Tylosin Tartrate.....10g Amantadin Hcl.....4.5g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,10Kg-De-Controlled,20GM-De-Controlled,25Kg-De-Controlled,500gm-De-Controlled,5KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. • Store at room temperature (25□C - 30□C) • Protect from direct sun light and heat.
	For generic drugs (me-too Status)	Amandx Powder (Reg. No 075778) 12. Name of company manufacturing in Pakistan. Leads Pharma (Pvt) Ltd. Islamabad
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Inspection was conducted on 23rd of December 2025 (Report copy Attached) Remarks of the Panels are as follows:- Based on the documentation reveiwed, technical/management people met, material/processes flow and detailed inspection of the stores, section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm was asked about target species, and they replied "target species Poultry".	
	Decision	
	Rejected	

	Rejected because firm applied for use in poultry.	
899	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(Q9G-X71-V4JW, 2026-03-24)
	Detail of Fee Submitted	38700, 2026-01-07,
	The proposed proprietary name / brand name	**Genoject-20 Injection 50ml**
	Label Claim	Each ml. contains Gentamycin as Sulphate USP.....200mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. • Store at room temperature (25□C - 30□C) • Protect from direct sun light and heat.
	For generic drugs (me-too Status)	G-Gen 200 Injection (Reg. # 111568) 8. Name of company manufacturing in Pakistan. Grand Pharmaceuticals (Pvt.) Ltd. Rawat
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Inspection was conducted on 23rd of December 2025 (Report copy Attached) Remarks of the Panels are as follows:- Based on the documentation reveiwed, technical/management people met, material/processes flow and detailed inspection of the stores, section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
900	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(RED-J7S-A77U, 2026-03-24)
	Detail of Fee Submitted	38700, 2026-01-07,
	The proposed proprietary name / brand name	**Genoject-20 Injection 100ml**
	Label Claim	Each ml. contains Gentamycin as Sulphate 200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore at cool and dry place. • Store at room temperature (25□C - 30□C) • Protect from direct sun light and heat.
	For generic drugs (me-too Status)	G-Gen 200 Injection (Reg. # 111568) 8. Name of company manufacturing in Pakistan. Grand Pharmaceuticals (Pvt.) Ltd. Rawat
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	Inspection was conducted on 23rd of December 2025 (Report copy Attached) Remarks of the Panels are as follows:- Based on the documentation reveiwed, technical/management people met, material/processes flow and detailed inspection of the stores, section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
901	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(SB2-PHP-PBM7, 2026-03-18)
	Detail of Fee Submitted	38700, 2026-01-07,
	The proposed proprietary name / brand name	**NEONOX-100 POWDER**
	Label Claim	Each gm. contains Neomycin Sulphate(BP).....1000 mg (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 KG-De-Controlled,10 Kg-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,20gm-De-Controlled,25 Kg-De-Controlled,5 Kg-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. • Store at room temperature (25□C - 30□C) • Protect from direct sun light and heat.
	For generic drugs (me-too Status)	NEOKAM-100 Powder (Reg. No. 119739) 12. Name of company manufacturing in Pakistan. M.A. KAMIL PHARMA (Pvt) Limited Karachi
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
902	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(TDW-YQA-VGXD, 2026-03-24)
	Detail of Fee Submitted	38700, 2026-01-07,

	The proposed proprietary name / brand name	**LEVAMIVIT-C LIQUID**
	Label Claim	Each ml. contains Levamisole Hcl BP.....1.5% Vitamin C BP.....0.025%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ML-De-Controlled,100ML-De-Controlled,120ML-De-Controlled,2.5 LITER-De-Controlled,25 LITER-De-Controlled,250ML-De-Controlled,5 LITER-De-Controlled,500ML-De-Controlled,50ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. • Store at room temperature (25□C - 30□C) • Protect from direct sun light and heat.
	For generic drugs (me-too Status)	Leva-C Liquid (Reg. No 062190) 12. Name of company manufacturing in Pakistan. Attabak Pharmaceutical Industries
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Inspection was conducted on 23rd of December 2025 (Report copy Attached) Remarks of the Panels are as follows:- Based on the documentation reveiwed, technical/management people met, material/processes flow and detailed inspection of the stores, section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
903	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)**
	Application Form Dy. No / Tracking ID & date of submission	(L2S-8RA-DVLZ, 2026-03-18)
	Detail of Fee Submitted	38700, 2026-03-11,
	The proposed proprietary name / brand name	**Te-Mox Powder**
	Label Claim	Each gram contains: Amoxicillin Trihydrate BP.....200mg Colistin Sulphate EP.....600000 IU (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,10 Kg-De-Controlled,100 gram-De-Controlled,2.5 Kg-De-Controlled,25 Kg-De-Controlled,250 gram-De-Controlled,5 Kg-De-Controlled,500 gram-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C in a cool and dry place. Protect form light
	For generic drugs (me-too Status)	Product Name: Cetamox Water Soluble Powder Registration No: 102096, by Decent Pharma, Rawat Islamabad
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	The management is highly inclined towards manufacturing good quality products by improving industry. The company is found complying satisfactory level of GMP as of today.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
904	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)**
	Application Form Dy. No / Tracking ID & date of submission	(618-VEW-54HA, 2026-01-09)
	Detail of Fee Submitted	38700, 9400 2026-01-07, 2026-08-05
	The proposed proprietary name / brand name	**Neosul-S Powder**
	Label Claim	Each 1000gm Contains Neomycin Sulphate BP.....600gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,2.5Kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)25-30 C
	For generic drugs (me-too Status)	Neo D 600 powder, DIVINE Pharmaceuticals, Reg. No: 084950
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML Renewal
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
905	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)**
	Application Form Dy. No / Tracking ID & date of submission	(BYL-DY5-M61X, 2026-01-09)
	Detail of Fee Submitted	38700, 9400 2026-01-07, 2026-08-05
	The proposed proprietary name / brand name	**Noramin S Liquid**
	Label Claim	Each 100ml Contains: Norfloxacin BP.....20gm Guaifenesin BP..... 20gm Aminophylline BP.....08gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,1Lit-De-Controlled,2.5Lit-De-Controlled,500ml-De-Controlled,5Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)25-30 C

	For generic drugs (me-too Status)	Nor Plus-20% Liquid, Bio-Labs, Regn. No: 033241
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML Renewal
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
906	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)**
	Application Form Dy. No / Tracking ID & date of submission	(M2M-8U6-UTAA, 2026-01-09)
	Detail of Fee Submitted	38700, 9400 2026-01-07, 2026-08-05
	The proposed proprietary name / brand name	**Brolinor Liquid**
	Label Claim	Each 100ml Contains Norfloxacin BP.....20gm Colistin sulphate BP..... 60MIU Bromhexine HCl BP.....0.5gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,1Lit-De-Controlled,2.5Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,5Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)25-30 C
	For generic drugs (me-too Status)	BROCONOR Liquid, Attabak pharma, Reg. No: 071067 (351 Meeting #729)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML Renewal
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
907	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)**
	Application Form Dy. No / Tracking ID & date of submission	(N2T-9SU-DRG5, 2026-01-09)
	Detail of Fee Submitted	38700, 9400 2025-12-11, 2026-08-05
	The proposed proprietary name / brand name	**Lenor-25 Liquid**
	Label Claim	Each 100ml contains: Norfloxacin BP.....25gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled,1Lit-De-Controlled,2.5Lit-De-Controlled,500ml-De-Controlled,5Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)25-30 C

	For generic drugs (me-too Status)	Noxabak 25 Liquid, Attabak pharma, Reg. No: 063828
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML Renewal
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
908	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)**
	Application Form Dy. No / Tracking ID & date of submission	(N67-4L5-YZ7S, 2026-01-09)
	Detail of Fee Submitted	38700, 9400 2025-12-11, 2026-08-05
	The proposed proprietary name / brand name	**Ave Linco 40% Powder**
	Label Claim	Each gm contains Lincomycin HCl e. q. to Lincomycin.....400mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100gm-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,2.5Kg-De-Controlled,25Kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)25-30 C
	For generic drugs (me-too Status)	Lincosel-40 powder, Selmore Pharmaceuticals, Reg. No: 089826
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML Renewal
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
909	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)**
	Application Form Dy. No / Tracking ID & date of submission	(P8U-HX3-P7YD, 2026-01-09)
	Detail of Fee Submitted	38700, 9400 2025-12-11, 2026-08-05
	The proposed proprietary name / brand name	**Ave Tylo 100 Powder**
	Label Claim	Each 100gm Contains Tylosin Tartrate BP.....100gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,2.5kg-De-Controlled,25Kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)25-30 C

	For generic drugs (me-too Status)	Tylolina 100% Powder, Alina Combine Pharmaceuticals, Reg. No: 069624
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML Renewal
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
910	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)**
	Application Form Dy. No / Tracking ID & date of submission	(T17-64Y-X4DM, 2026-01-09)
	Detail of Fee Submitted	38700, 9400 2026-01-07, 2026-08-05
	The proposed proprietary name / brand name	**Lezoltin Liquid**
	Label Claim	Each 100 ml contains: Triclabendazole BP.....12gm Ivermectin USP.....0.2gm Albendazole.....10gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,1Lit-De-Controlled,2.5Lit-De-Controlled,500ml-De-Controlled,5Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)25-30 C
	For generic drugs (me-too Status)	THUNDER Drench, STAR LABORATORIES, Reg. No: 058941
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML Renewal
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
911	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)**
	Application Form Dy. No / Tracking ID & date of submission	(V83-UHA-VX8G, 2026-01-09)
	Detail of Fee Submitted	38700, 9400 2026-01-07, 2026-08-05
	The proposed proprietary name / brand name	**Leconor Liquid**
	Label Claim	Each 100 ml contains Norfloxacin BP.....20gm Colistin sulphate..... 50MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,1Lit-De-Controlled,2.5Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,5Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)25-30 C

	For generic drugs (me-too Status)	Colinor Liquid, Attabak pharma, Reg. No: 071066 (351 Minutes #764)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML Renewal
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
912	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)**
	Application Form Dy. No / Tracking ID & date of submission	(WLX-437-QD8S, 2026-01-09)
	Detail of Fee Submitted	38700, 9400 2025-12-11, 2026-08-05
	The proposed proprietary name / brand name	**Lemectin Liquid**
	Label Claim	Each ml contains: Ivermectin USP.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,1Lit-De-Controlled,2.5Lit-De-Controlled,500ml-De-Controlled,5Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)25-30 C
	For generic drugs (me-too Status)	FARO-MAC Liquid, MALLARD Pharmaceuticals, Reg. No: 058915
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML Renewal
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
913	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)**
	Application Form Dy. No / Tracking ID & date of submission	(WSY-4L3-BBG9, 2026-01-09)
	Detail of Fee Submitted	38700, 9400 2025-12-11, 2026-08-05
	The proposed proprietary name / brand name	**Ledotil-30% Liquid**
	Label Claim	Each ml contains Tilmicosin phosphate USP.....300 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,1Lit-De-Controlled,2.5Lit-De-Controlled,500ml-De-Controlled,5Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)25-30 C
	For generic drugs (me-too Status)	TILOMED 30% Liquid, UNICARE ENTERPRISES, Reg. No: 125900

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML Renewal
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
914	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)**
	Application Form Dy. No / Tracking ID & date of submission	(X3L-LNV-DY7B, 2026-01-09)
	Detail of Fee Submitted	38700, 9400 2026-01-07, 2026-08-05
	The proposed proprietary name / brand name	**Ledonor ST Liquid**
	Label Claim	Each 100 ml contains: Norfloxacin BP.....10gm Sulphamethoxy pyridazine BP.....15gm Trimethoprim BP.....03gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1Lit-De-Controlled,2.5Lit-De-Controlled,500ml-De-Controlled,5Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)25-30 C
	For generic drugs (me-too Status)	Nor Plus Liquid, Attabak pharma, Reg. No: 034534
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML Renewal
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
915	Case Category	Routine (Sara Mehreen)
	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	(H4R-YV6-J171, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**ENRO-SAL 20 W/S Powder**
	Label Claim	Each 100 gm Contain Enrofloxacin HCL ... ... 20gm (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000g-De-Controlled,100g-De-Controlled,250g-De-Controlled,500g-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30c°
	For generic drugs (me-too Status)	ENSTER 20% ORAL WATER SOLUBLE POWDER (101502) M/S AAMSTER LABORATORIES, RAWAT, ISLAMABAD
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for grant of drug manufacturing licence(by way of formulation)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
916	Case Category	Routine (Sara Mehreen)
	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	(P7Z-6RW-25QD, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**SAL-VIR-1**
	Label Claim	Each 1000gm Contains; Amantadine HCl BP.....10gm (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000g-De-Controlled,100g-De-Controlled,150g-De-Controlled,250g-De-Controlled,500g-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	AMSTERDINE-1 WATER SOLUBLE POWDER (Reg. No. 101996) M/S AAMSTER LABORATORIES RAWAT, ISLAMABAD LUBLE POWDER (Reg. No. 101996)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for grant of drug manufacturing licence(by way of formulation)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has mentioned target species as non-food producing animals e.g. cats, dogs, horses. Approved pack size is 100g only.	
	Decision	
	Approved	
917	Case Category	Routine (Sara Mehreen)
	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	(AJZ-MVA-9J5P, 2026-01-07)
	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**Dorantil Solution for Injection 100ML**
	Label Claim	Each ml contains: Doramectin 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Yearbelow 30

	For generic drugs (me-too Status)	Mecdor Injection (Reg No. 097874)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	based on the stated observation their current GMP compliance level is rated as Good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
918	Case Category	Routine (Sara Mehreen)
	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	(DZU-1PY-N83S, 2026-01-08)
	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**Ketowan Injection 10ML**
	Label Claim	Each ml contains: Ketoprofen.....100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 Yearbelow 25
	For generic drugs (me-too Status)	Ketovet Injection (Reg No. 088156)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	based on the stated observation their current GMP compliance level is rated as Good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
919	Case Category	Routine (Sara Mehreen)
	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	(EXA-GNB-NMGQ, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-23,
	The proposed proprietary name / brand name	**Benzastrep Injection 50ml**
	Label Claim	Each ml Contains: Benzathine Penicillin G USP..... 100,000 IU Procaine Penicillin G USP..... 150,000 IU Dihydrostreptomycin Sulphate eq.to Dihydrostreptomycin BP..... 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)below 25
	For generic drugs (me-too Status)	BPS-LA Injection (Reg No. 080951)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	based on the stated observation their current GMP compliance level is rated as Good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
920	Case Category	Routine (Sara Mehreen)
	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	(MVZ-VEH-ZW1G, 2025-11-26)
	Detail of Fee Submitted	38700, 2025-11-25,
	The proposed proprietary name / brand name	**Cefanil Injection 100ml**
	Label Claim	Each ml contains: Cefquinome (as Sulfate).....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)below 25
	For generic drugs (me-too Status)	Cefanome Injection (Reg No. 114797)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	based on the stated observation their current GMP compliance level is rated as Good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
921	Case Category	Routine (Sara Mehreen)
	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	(NHT-BQB-VZME, 2025-11-26)
	Detail of Fee Submitted	38700, 2025-11-25,
	The proposed proprietary name / brand name	**Marbowan Injection 100ML**
	Label Claim	Each ml contains: Marbofloxacin BP.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)below 25
	For generic drugs (me-too Status)	Marbo-Vetz 10% Injection (Reg No. 099432)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	based on the stated observation their current GMP compliance level is rated as Good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
922	Case Category	Routine (Sara Mehreen)
	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	(WN5-S25-AZL7, 2026-01-07)
	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**Dorantil Solution for Injection 10ML**
	Label Claim	Each ml contains: Doramectin 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 Yearbelow 30
	For generic drugs (me-too Status)	Doramax Injection (Reg No.088125)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	based on the stated observation their current GMP compliance level is rated as Good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
923	Case Category	Routine (Sara Mehreen)
	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	(2ST-PWB-7PZW, 2025-11-06)
	Detail of Fee Submitted	38700, 2025-10-17,
	The proposed proprietary name / brand name	**TRI PHATE DRENCH**
	Label Claim	Each 100 ml Contains: Triclabendazole BP.....5g Levamisole HCl BP.....3.75 g Cobalt Chloride BP.....0.075 g Sodium Selenite BP.....0.035 g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,20ml-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Tremafex Drench 8.75 % M/S Leads Pharma (Pvt). Ltd Reg. No: (031471)
	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	
924	Case Category	Routine (Sara Mehreen)
	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	(3PU-NNN-V6XH, 2025-09-21)
	Detail of Fee Submitted	38700, 2025-08-26,
	The proposed proprietary name / brand name	**NCO-TAL 200 Powder**
	Label Claim	Each gm. Contains: Oxytetracycline HCl BP.....200 mg Colistin Sulphate BP.....0.24 MIU Neomycin Sulphate BP....200 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,100gm-De-Controlled,15 kg-De-Controlled,20 kg-De-Controlled,25 kg-De-Controlled,250gm-De-Controlled,5 kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Acme NOC 20/20/0.24 Water Soluble Powder M/S ACME Pharmaceuticals (pvt) LTD DML: 000967 Reg No: 117038
	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	
925	Case Category	Routine (Sara Mehreen)
	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	(8GA-W4M-4343, 2025-11-06)
	Detail of Fee Submitted	38700, 2025-10-17,
	The proposed proprietary name / brand name	**HARRYZEN DS 1000ml Oral SUSPENSION**
	Label Claim	Each 100 ml Contains: Oxyclozanide BP.....3.0 gm. Levamisole HCl BP.....1.5 gm. Cobalt Sulphate.....0.167 gm. Selenium Selenite BP.....0.050 gm.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,20ml-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,5 Litter-De-

		Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	GULZAN PLUS ORAL SUSPENSION M/S INTERNATIONAL PHARMA LABS (Pvt). Ltd Reg. No: (049656)
	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	
926	Case Category	Routine (Sara Mehreen)
	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	(ER3-JSJ-JQ66, 2025-09-21)
	Detail of Fee Submitted	38700, 2025-08-26,
	The proposed proprietary name / brand name	**NCO-TAL 300 Powder**
	Label Claim	Each gm. Contains: Oxytetracycline HCl BP...300 mg. Colistin Sulphate BP.....0.5 MIU. Neomycin Sulphate BP.....250 mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,100gm-De-Controlled,15 kg-De-Controlled,20 kg-De-Controlled,25 kg-De-Controlled,250gm-De-Controlled,5 kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Acme NOC 30/25/0.5 water soluble powder M/S ACME Pharmaceuticals (pvt) LTD DML: 000967 Reg No: 117041
	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	
927	Case Category	Routine (Sara Mehreen)
	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	(ER6-RDS-WSXD, 2025-11-06)
	Detail of Fee Submitted	38700, 2025-10-17,

	The proposed proprietary name / brand name	**HAN-FAXS DRENCH**
	Label Claim	Each 100 ml Contains: Triclabendazole BP.....12 gm. Ivermectin BP.....0.2 gm. Albendazole BP.....10 gm.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,20ml-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Each 100 ml Contains: Triclabendazole ……12 gm. Ivermectin……0.2 gm. Albendazole……10 gm.
	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	
928	Case Category	Routine (Sara Mehreen)
	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	(NGR-N1W-NMZE, 2025-09-21)
	Detail of Fee Submitted	38700, 2025-08-26,
	The proposed proprietary name / brand name	**FENICOL C-25 Liquid**
	Label Claim	Each ml Contains: FLORFENICOL..... 250 mg. COLISTIN SULPHATE BP... 0.50 MIU.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,30ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,60ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Florocol-25 Oral Liquid M/S ACME Pharmaceuticals (pvt) LTD DML No: 000967 Regd No: 117029
	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	
929	Case Category	Routine (Sara Mehreen)
	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	(LUV-EVZ-MEWH, 2025-09-21)
	Detail of Fee Submitted	38700, 2025-08-26,
	The proposed proprietary name / brand name	**FENICOL C-11 Liquid**
	Label Claim	Each ml Contains: FLORFENICOL.....110 mg. COLISTIN SULPHATE BP.... 0.50 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,30ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,60ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Florocol-11 Oral Liquid M/S ACME Pharmaceuticals (pvt) LTD DML No: 000967 Regd No: 117027
	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	
930	Case Category	Routine (Sara Mehreen)
	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	(PNB-EWA-7GJY, 2025-09-21)
	Detail of Fee Submitted	38700, 2025-08-26,
	The proposed proprietary name / brand name	**FENICOL C-23 Liquid**
	Label Claim	Each 100 ml Contains: FLORFENICOL..... 23 gm. COLISTIN SULPHATE BP.... 50 MIU.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,30ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,60ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature

	For generic drugs (me-too Status)	Colfen 23% Oral Liquid M/S BIO-LABS PHARMACEUTICALS (pvt.) Ltd DML No: 00930 Regd No: 112225
	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	
931	Case Category	Routine (Sara Mehreen)
	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	(X2E-E4Q-X279, 2025-09-21)
	Detail of Fee Submitted	38700, 2025-08-26,
	The proposed proprietary name / brand name	**NCO-TAL 500 Powder**
	Label Claim	Each gm. Contains: Oxytetracycline HCl BP.....200 mg Colistin Sulphate BP.....0.55 MIU Neomycin Sulphate BP.....200 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,100gm-De-Controlled,15 kg-De-Controlled,20 kg-De-Controlled,25 kg-De-Controlled,250gm-De-Controlled,5 kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Acme NOC 20/20/0.55 Water Soluble Powder M/S ACME Pharmaceuticals (pvt) LTD DML: 000967 Reg No: 117040
	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	
932	Case Category	Routine (Sara Mehreen)
	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	(X9J-YQH-D3JA, 2025-11-06)
	Detail of Fee Submitted	38700, 2025-10-17,
	The proposed proprietary name / brand name	**BEN ROLD 10% DRENCH**
	Label Claim	Each ml Contains: ALBENDAZOLE BP.....100 mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,30ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,60ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Albensel-10 Drench M/S SELMOR Pharmaceutical (pvt) LTD Reg. No: (043143)
	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	
933	Case Category	Routine (Sara Mehreen)
	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	(Z8R-JMM-315H, 2025-11-06)
	Detail of Fee Submitted	38700, 2025-10-17,
	The proposed proprietary name / brand name	**AMSENIDE ORAL SUSPENSION**
	Label Claim	Each ml Contains: Oxyclozanide BP.....62.5 mg Oxfendazole BP.....22.65 mg Cobalt Sulphate.....1.67 mg Sodium Selenite BP.....0.5 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Litter-De-Controlled,100ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,20ml-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	FEN PLUS ORAL SUSPENSION
	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	
934	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	(G6L-QRJ-1X27, 2025-11-24)
	Detail of Fee Submitted	38700, 2025-11-20,
	The proposed proprietary name / brand name	**NORCOL P ORAL LIQUID**
	Label Claim	Each 100 ml contains:- Norfloxacin BP- 20gm, Colistin Sulphate BP- 60 M.I.U
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,10ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Coli-Nor Liquid of Leads Pharma (Reg#049501)
	Pharmacotherapeutic Group of (API)	
	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	
	Approved	
935	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	(L5W-WXE-TTLX, 2025-11-24)
	Detail of Fee Submitted	38700, 2025-11-20,
	The proposed proprietary name / brand name	**POUL STREP ON POWDER**
	Label Claim	Each gm contains:- Neomycin Sulphate BP- 60mg, Oxytetracycline HCl BP 200mg, Streptomycin Sulphate BP- 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10000gm-De-Controlled,1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,25000gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Sondex Vet Dry Powder of Biorific Pharma (Reg # 088318)
	Pharmacotherapeutic Group of (API)	
	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	
	Approved	
936	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	(NXR-4B7-JPTR, 2025-11-24)
	Detail of Fee Submitted	38700, 2025-11-20,
	The proposed proprietary name / brand name	**NECOX-50 WATER SOLUBLE POWDER**
	Label Claim	EACH 1000gm contains:- Neomycin Sulphate BP - 250gm , Colistin Sulphate BP- 300 M.I.U , Oxytetracycline HCl BP- 250gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,20gm-De-Controlled,2500gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)AT ROOM TEMPERATURE
	For generic drugs (me-too Status)	ONC FORTE POWDER OF M/S NOBLE PHARMA (REG # 078217)
	Pharmacotherapeutic Group of (API)	
	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	
	Approved	
937	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**PRIX PHARMACEUTICA (PRIVATE) LIMITED** PLOT NO.5 PHARMACITY, 30-KM MULTAN ROAD, LAHORE **(000587)**

	Application Form Dy. No / Tracking ID & date of submission	(8NH-67Y-48YS, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-01-29,
	The proposed proprietary name / brand name	**Allerphen Injection(Vet) 30ml**
	Label Claim	Allerphen Injection(Vet) Pack 30ml Each ml Injection contains; Chlorpheniramine Maleate (BP)----------25mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	30 ml Vial-De-Controlled
	Shelf Life (Unit)	2 YearStore between 15C ---30C
	For generic drugs (me-too Status)	Phenergic-M Injection Reg.#: 043163 (Pack size 30ml) Leeds Pharma Islamabad
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Authorization of production of medicine in all approved sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
938	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**PRIX PHARMACEUTICA (PRIVATE) LIMITED** PLOT NO.5 PHARMACITY, 30-KM MULTAN ROAD, LAHORE **(000587)**
	Application Form Dy. No / Tracking ID & date of submission	(VJ7-L1A-A2PA, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-01-29,
	The proposed proprietary name / brand name	**Allerphen Injection(Vet). 100ml**
	Label Claim	Allerphen Inj.(Vet) 100ml pack size Each ml contains: Chlorpheniramine Maleate (BP)----------25ml
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ml glass vial-De-Controlled
	Shelf Life (Unit)	2 YearStore between 15C ---30C
	For generic drugs (me-too Status)	Phenergic-M Injection Reg.#: 043163 (100ml pack size) Leeds Pharma Islamabad
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Authorization of production of medicine in all approved sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
939	Case Category	Routine (Sara Mehreen)
	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	(7UE-B86-VBVM, 2025-09-10)
	Detail of Fee Submitted	38700.0, 2025-09-04,
	The proposed proprietary name / brand name	**Ketto Injection 100mL**
	Label Claim	Each mL contains: Ketoprofen BP.....100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)As per Zone IVA
	For generic drugs (me-too Status)	Ketovet Injection by Vetz Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The Facility of M/s. S.J&G Fazul Ellahie, Karachi was found to be operating in compliance with the requirement of GMP.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
940	Case Category	Routine (Sara Mehreen)
	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	(MP4-5G7-DLHG, 2025-09-27)
	Detail of Fee Submitted	38700, 2025-09-25,
	The proposed proprietary name / brand name	**Flunox Injection**
	Label Claim	Each mL contains: Oxytetracycline (as dihydrate) .....300mg Flunixin Meglumine eq. to Flunixin.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)As per Zone IVA
	For generic drugs (me-too Status)	Nimtol Injection by Nawan Laboratories
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The Facility of M/s. S.J&G Fazul Ellahie, Karachi was found to be operating in compliance with the requirement of GMP.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
941	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	(387-URH-44YW, 2025-12-04)

	Detail of Fee Submitted	37000, 1700 2025-08-06, 2026-07-09
	The proposed proprietary name / brand name	**Dinax powder**
	Label Claim	Each gm contains: Danofloxacin as Mesylate.....100mg
	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 Yearstore below 30C.
	For generic drugs (me-too Status)	DONAM POWDER(REG.102184)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	inspection pennel recommended the renewal of dml and gmp.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
942	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	(ENS-U3E-BJXH, 2025-10-06)
	Detail of Fee Submitted	37000, 1700 2025-08-06, 2026-07-09
	The proposed proprietary name / brand name	**Prevecox-98 Powder**
	Label Claim	Each gm contains: Amprolium HCl USP.....980mg (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.
	For generic drugs (me-too Status)	Ampro-98 Oral Powder Reg. # 083241
	Pharmacotherapeutic Group of (API)	
	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	
	Evaluation Remarks	
	Decision	
	Approved	
943	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	(MGU-D2J-69YR, 2025-08-08)

	Detail of Fee Submitted	37000.0, 1700 2025-08-06, 2026-07-09
	The proposed proprietary name / brand name	**Diadin Powder**
	Label Claim	Each gm contains: Sulphadimerazine .....860mg Diaveridine .....105mg (Innovator's Specification)
	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 YearStore below 25°C.
	For generic drugs (me-too Status)	Dialpha Powde Reg. # 053977
	Pharmacotherapeutic Group of (API)	
	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	
	Evaluation Remarks	
	Decision	
	Approved	
944	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	(X23-USY-L84D, 2025-09-02)
	Detail of Fee Submitted	37000.0, 1700 2025-08-21, 2026-07-09
	The proposed proprietary name / brand name	**Macrolin Plus Powder**
	Label Claim	Each kg contains:- Tylosin tartrate BP .....100gm Colistin Sulphate BP.....240MIU (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.
	For generic drugs (me-too Status)	Xylostin Powder Reg. # 049797
	Pharmacotherapeutic Group of (API)	
	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	
	Evaluation Remarks	
	Decision	

	Approved	
945	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	(Z9A-8WM-324Y, 2025-10-06)
	Detail of Fee Submitted	37000, 1700 2025-08-06, 2026-07-09
	The proposed proprietary name / brand name	**Neoton Extra Powder**
	Label Claim	Each kg contains: Neomycin Sulphate.....1000gm (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 YearStore below 25°C.
	For generic drugs (me-too Status)	Neo-S 100 Powder Reg. # 088862
	Pharmacotherapeutic Group of (API)	
	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	
	Evaluation Remarks	
	Decision	
	Approved	
946	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	(JDY-S12-JWDS, 2025-09-02)
	Detail of Fee Submitted	37000.0, 1700 2025-08-19, 2026-07-09
	The proposed proprietary name / brand name	**Vitsalt Powder**
	Label Claim	Each 1000 gm contains: Vitamin A.....11500000IU Vitamin D3.....1800000IU Vitamin E.....5200IU Vitamin B2.....1200mg Cal.D.Pantothenate.....10000mg Folic Acid.....200mg Biotin.....10mg Sodium Chloride.....200mg Potassium Chloride.....1600mg Zinc Sulphate.....10000mg Magnesium Sulphate.....10000mg L-lysine HCl.....10000mg DL-Methionine.....10000mg (Innovator's Specification)

	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 YearStore below 25°C.
	For generic drugs (me-too Status)	Biolyte Water Soluble Powder Reg. # 014534
	Pharmacotherapeutic Group of (API)	
	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	
	Evaluation Remarks	
	Decision	
	Approved	
947	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	(T61-Q76-8NGH, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-02-03,
	The proposed proprietary name / brand name	**CILLIBECT ORAL POWDER**
	Label Claim	Each 100 gm Powder Contains Amoxicillin As Trihydrate (BP).... 50gm Colistin Sulphate (BP).....50MIU Product complies with Innovator’s specs.
	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,25000 gm-De-Controlled,500 gm-De-Controlled,5000 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)below 25 degree
	For generic drugs (me-too Status)	Approved
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and the review of the production facilities, building, equipment, quality control and quality assurance, the
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
948	Case Category	Routine (Sara Mehreen)
	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	(XHU-BDJ-TXUH, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-09,
	The proposed proprietary name / brand name	**Tymu 45% Oral Powder**
	Label Claim	Each 100 g contains Tiamulin Hydrogen Fumerate (USP) equivalent to Tiamulin base ..... 45 g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30g, 50g,100g, 250g, 500g, 1000g, 5000g, 10,000g, 25,000g-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store at controlled room temperature.
	For generic drugs (me-too Status)	SB Tiamulin 45% Oral Powder Reg. No. 048221
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Yes
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
949	Case Category	Routine (Sara Mehreen)
	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	(SD1-93B-M41V, 2026-01-01)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**FLOR-OX-N ORAL POWDER**
	Label Claim	Each gm contains (As Per Innovators Spec.) Oxytetracycline HCl BP 300mg Florfenicol 100mg Neomycin sulphate BP 150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled,Kg-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	NEOXFLOR ORAL POWDER (088638) BAARIQ PHARMA
	Pharmacotherapeutic Group of (API)	
	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	
950	Case Category	Routine (Sara Mehreen)
	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	(UB6-XS1-BVT6, 2026-01-01)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**STINO-FORD 23% ORAL LIQUID**
	Label Claim	Each 1000ml contains (As Per Innovator Spec.) Florfenicol USP..... 230g Colistin sulphate BP..... 500MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,1Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Z-FLORCOL ORAL LIQUID (080940) ZOIC PHARMA LAHORE
	Pharmacotherapeutic Group of (API)	
	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	
951	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)**
	Application Form Dy. No / Tracking ID & date of submission	(1WH-B8A-3EQV, 2026-02-02)
	Detail of Fee Submitted	38700, 2026-01-20,
	The proposed proprietary name / brand name	**Aminoplex Forte Injectable Solution**
	Label Claim	Each 100 ml contains: Dextrose (USP).....5.5g, Calcium Chloride(USP) .....15.00mg, Potassium Chloride(USP)..... 20.00mg, Magnesium Sulphate(USP) .....20.00mg, Sodium Acetate Trihydrate(USP) .....250.0mg, L-histidine hydrochloride (BP).....34.00mg, DL-Methionine(BP) .....34.00mg, DL-Tryptophane(USP) .....34.00mg, L- Threonine(USP) .....68.00mg, L-Cysteine Hydrochloride(USP) .....34.00mg, DL-Isoleucine(USP) .....68.00mg, L-Arginine Hydrochloride (USP).....85.00mg, DL-Phenylalanine(USP) .....102.0mg, DL-Valine (USP).....170.0mg, L-Lysine hydrochloride(USP) .....102.0mg, L-leucine(USP) .....136.0mg, Monosodium glutamate(USP).....136.0mg,

		Vitamin B1 (Thiamine HCl)(USP) .....10.00mg, Vitamin B2 (Riboflavin sodium Phosphate) (USP)....4.00mg, Vitamin B6 (Pyridoxine HCl) (USP) .....10.00mg, Vitamin B12 (Cyanocoblamin)(USP) .....5.00mcg, Niacinamide(USP) .....150mg, Benzyl Alcohol(USP) .....1.5g, Sterile osmotized water q.s.ad. 100ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)<30C
	For generic drugs (me-too Status)	Imported By Mustafa Brothers
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
952	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)**
	Application Form Dy. No / Tracking ID & date of submission	(3YV-XY7-SSL1, 2026-01-27)
	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**Dprost Liquid Injection**
	Label Claim	Each mL Contains:- Dinoprost as Trometamol USP.....5MG
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5 mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)<25C
	For generic drugs (me-too Status)	Selmore Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

953	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)**
	Application Form Dy. No / Tracking ID & date of submission	(4ER-3NS-N5N2, 2025-09-01)
	Detail of Fee Submitted	38700.0, 2025-08-20,
	The proposed proprietary name / brand name	**AG-FLOX ORAL LIQUID**
	Label Claim	EACH ML CONTAINS Enrofloxacin BP.....100mg Aminophylline BP.....40mg Guaiphenesin BP.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 mL-De-Controlled,1000 mL-De-Controlled,10000 mL-De-Controlled,120 mL-De-Controlled,250 mL-De-Controlled,2500 mL-De-Controlled,25000 mL-De-Controlled,30 mL-De-Controlled,50 mL-De-Controlled,500 mL-De-Controlled,5000 mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)<30C
	For generic drugs (me-too Status)	ACME PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
954	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)**
	Application Form Dy. No / Tracking ID & date of submission	(9WZ-NA1-G5GY, 2025-09-01)
	Detail of Fee Submitted	38700.0, 2025-08-20,
	The proposed proprietary name / brand name	**COXYDIA ORAL POWDER**
	Label Claim	Each 1000 GRAM Contains: Sulphaquinoxaline Sodium USP.....200 G Sulphadimidine Sodium BP.....82.5 G Diaverdine HCL.....40 G Vitamin K3 USP.....2 G Vitamin A USP.....2.8 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 KG-De-Controlled,100 G-De-Controlled,500 G-De-Controlled
	Shelf Life (Unit)	2 Year(s)<30C
	For generic drugs (me-too Status)	BIOGEN PHARMA
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	--
	GMP status of the firm	In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
955	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)**
	Application Form Dy. No / Tracking ID & date of submission	(E12-YGR-28J7, 2025-09-11)
	Detail of Fee Submitted	37000.0, 12500 2025-06-19, 2026-08-12
	The proposed proprietary name / brand name	**FORMAPEN LA INJECTION**
	Label Claim	Each ml contains Amoxicilline Trihydrate BP... 150 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10 mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)<30C
	For generic drugs (me-too Status)	COMPANY MANUFACTURING : CHERISHED PHARMACEUTICALS (PRIVATE) LTD , BRAND NAME: Amoxygem Injection , DRAP REG. NO. 063506
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
956	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)**
	Application Form Dy. No / Tracking ID & date of submission	(MQ1-GZW-RY43, 2025-09-01)
	Detail of Fee Submitted	38700.0, 2025-08-20,
	The proposed proprietary name / brand name	**HEXTHOL LIQUID**
	Label Claim	Each mL Contains Bromhexine HCl USP..... 50 mg Menthol BP.....40 mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 L-De-Controlled,100 mL-De-Controlled,250 mL-De-Controlled,500 mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)<30C
	For generic drugs (me-too Status)	NAWAL PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
957	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)**
	Application Form Dy. No / Tracking ID & date of submission	(RX8-JTE-MAMA, 2025-09-01)
	Detail of Fee Submitted	38700.0, 2025-08-20,
	The proposed proprietary name / brand name	**FENIX WATER SOLUBLE POWDER**
	Label Claim	Each GRAM Contains Florfenicol.....150mg Oxytetracycline HCl USP..... 150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 G-De-Controlled,1000 G-De-Controlled,10000 G-De-Controlled,250 G-De-Controlled,2500 G-De-Controlled,25000 G-De-Controlled,500 G-De-Controlled,5000 G-De-Controlled
	Shelf Life (Unit)	2 Year(s)<30C
	For generic drugs (me-too Status)	AAMSTER LABORATORIES
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
958	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)**

	Application Form Dy. No / Tracking ID & date of submission	(UEQ-957-TURA, 2025-11-24)
	Detail of Fee Submitted	38700, 38700 2025-08-20, 2026-06-23
	The proposed proprietary name / brand name	**MERAMIN INJECTION**
	Label Claim	Each ml contains: Mepyramine Maleate BP.....50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)<30C
	For generic drugs (me-too Status)	(MEPRASON INJECTION) by STAR LABORATORIES (PVT) LTD
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In view of above inspection proceedings, and facilities verified such as company profile. building. production, in-process controls, quality control testing, machinery/ equipment, material management, air handling, water treatment system, personnel and d
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
959	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)**
	Application Form Dy. No / Tracking ID & date of submission	(X1B-W9U-6E16, 2025-09-01)
	Detail of Fee Submitted	38700.0, 2025-08-20,
	The proposed proprietary name / brand name	**Dyecox Water Soluble Powder**
	Label Claim	Each gm Contains Amprolium HCl USP.....300mg Sulphaquinoxaline Sodium USP.....200mg Vitamin K3 USP.....6mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 KG-De-Controlled,10 KG-De-Controlled,100 G-De-Controlled,2.5 KG-De-Controlled,25 KG-De-Controlled,5 KG-De-Controlled,500 G-De-Controlled
	Shelf Life (Unit)	2 Year(s)<30C
	For generic drugs (me-too Status)	DECENT PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
960	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)**
	Application Form Dy. No / Tracking ID & date of submission	(JAE-1GE-HT78, 2025-09-01)
	Detail of Fee Submitted	38700.0, 2025-08-20,
	The proposed proprietary name / brand name	**BDEX Liquid Injection**
	Label Claim	Each mL Contains Benzyl penicillin procaine (BP).....125.000 I.U Benzyl penicillin benzathine (BP).....125,000 I.U Dihydro streptomycin sulphate (BPVET).....0.25gm. (equivalent to dihydrostreptomycin0.20gm). Dexamethasone sodium phosphate (BP).....0.20mg Dexamethasone21-isonicotinate (BP).....0.20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)<30C
	For generic drugs (me-too Status)	SELMORE PHARMACEUTICALS (PVT.) LTD.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
961	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)**
	Application Form Dy. No / Tracking ID & date of submission	(XM6-GAQ-3WB3, 2025-08-08)
	Detail of Fee Submitted	38700.0, 2025-08-08,
	The proposed proprietary name / brand name	**THIPESING INJECTION**
	Label Claim	Each ml contains: Thiamphenicol ..... 200 mg Tylosin Tartrate USP..... 57.5 mg Prednisolone Acetate USP..... 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20 mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)<30C
	For generic drugs (me-too Status)	SELMORE AGENCIES PVT. LTD. LAHORE
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	--
	GMP status of the firm	In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
962	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)**
	Application Form Dy. No / Tracking ID & date of submission	(YL7-QYL-WJ61, 2025-09-01)
	Detail of Fee Submitted	38700.0, 2025-08-20,
	The proposed proprietary name / brand name	**B.G Suntol Water Soluble Powder**
	Label Claim	Each 100gm Contains: Coumaphos .....50g As per Innovator's Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 KG-De-Controlled,100gm-De-Controlled,15gm x 10box-De-Controlled,15gm x 25box-De-Controlled,15gm-De-Controlled,250gm-De-Controlled,500gm -De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)<30C
	For generic drugs (me-too Status)	SELMORE PHARMACEUTICALS (PVT.) LTD. , BIOGEN PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
963	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)**
	Application Form Dy. No / Tracking ID & date of submission	(T26-18M-YPGR, 2026-02-02)
	Detail of Fee Submitted	38700, 2026-01-21,
	The proposed proprietary name / brand name	**Aminoplex Forte Injectable Solution**

	Label Claim	Each 100ml contains: Dextrose (USP).....5.5g, Calcium Chloride (USP) .....15.00mg, Potassium Chloride (USP)..... 20.00mg, Magnesium Sulphate (USP) .....20.00mg, Sodium Acetate Trihydrate (USP) .....250.0mg, L-histidine hydrochloride (BP).....34.00mg, DL-Methionine (BP) .....34.00mg, DL-Tryptophane (USP) .....34.00mg, L- Threonine (USP) .....68.00mg, L-Cysteine Hydrochloride (USP) .....34.00mg, DL-Isoleucine (USP) .....68.00mg, L- Arginine Hydrochloride (USP).....85.00mg, DL-Phenylalanine (USP) .....102.0mg, DL-Valine (USP).....170.0mg, L-Lysine hydrochloride (USP) .....102.0mg, L-leucine (USP) .....136.0mg, Monosodium glutamate (USP).....136.0mg, Vitamin B1 (Thiamine HCl) (USP) .....10.00mg, Vitamin B2 (Riboflavin sodium Phosphate) (USP)....4.00mg, Vitamin B6 (Pyridoxine HCl) (USP) .....10.00mg, Vitamin B12 (Cyanocoblamin) (USP) .....5.00mcg, Niacinamide (USP) .....150mg, Benzyl Alcohol (USP) .....1.5g, Sterile osmotized water q.s.ad. 100ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)<30C
	For generic drugs (me-too Status)	Imported By Mustafa Brothers
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
964	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)**
	Application Form Dy. No / Tracking ID & date of submission	(2TN-W1H-YQ7G, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-27,
	The proposed proprietary name / brand name	**BIOSON INJECTION**
	Label Claim	Each ml contains: Novaminsulfon ... 40mg Etilefrin as HCl ... 0.2mg Calcium gluconate ... 100mg Magnesium gluconate ... 10mg Sodium

		salicylate ... 7mg Nicotinamide ... 0.3mg Caffeine ... 10mg Boric acid ... 10mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	250ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC
	For generic drugs (me-too Status)	Pri-Sedaxvit Inj (250ml) of M/s. Prix Pharma (Reg.No.079256)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	As per letter No. F.5-1/2019-Lic. dated 28 August 2023, firm has been granted approval of Liquid Injection Section Vet. (General). However, firm has applied for Injection Pack Size of 250ml. The said letter suggests that firm has approval only for SVP. Therefore, firm may be advised to regularize/ obtain requisite approval for the relevant section (LVP) through Licensing Division before the approval of applied formulation. Submitted for consideration of the Board, please.	
	Decision	
	Deferred Deferred for confirmation of manufacturing facility for Large Volume Parenteral (LVP) from Division of Drug Licensing.	
965	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	(B78-NQZ-BA8S, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**BRIFITO INJECTION**
	Label Claim	Each ml contains Diminazene Aceturate ..... 105mg Antipyrine USP..... 131mg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	Pyraminol Injection. (075676)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
966	Case Category	Routine (Sara Mehreen)
	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	(7J5-URV-ZEM2, 2025-07-26)
	Detail of Fee Submitted	37000.0, 2025-07-24,
	The proposed proprietary name / brand name	**Nugmentan Powder**
	Label Claim	Each gram Contains: Amoxicillin (as Trihydrate) BP..... 160mg Clavulanic Acid (as Potassium Clavulanate BP) 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2.5kg, 5kg & 10kg - De-Controlled
	Shelf Life (Unit)	2 Year(s)below 25
	For generic drugs (me-too Status)	Clavet Powder
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	based on the stated observation their current GMP compliance level is rated as Good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	As per letter No. F.2-10/93-Lic (Vol-I) dated 07 June 2022, firm has been granted approval of Dry Powder Sachet (Penicillin) Vet. However, firm has applied for Pack Sizes as 100gm, 250gm, 500gm, 1kg, 2.5kg, 5kg & 10kg with laminated metalized foil pouches and plastic woven bags as proposed container-closure system, Batch Size as 20 KG (20 Bags) and Fill Volume as 1Kg. The said letter suggests that firm has approval only for Sachet. Therefore, firm may be advised to regularize/ obtain requisite approval for the relevant manufacturing section through Licensing Division before the approval of applied formulation. Submitted for consideration of the Board, please.	
	Decision	
	Deferred Deferred for clarification of manufacturing section/ facility from Drug Licensing Division, DRAP.	
967	Case Category	Routine (Sara Mehreen)
	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	(LSB-9ZW-ZAYH, 2025-07-26)
	Detail of Fee Submitted	37000.0, 2025-07-24,
	The proposed proprietary name / brand name	**Amoclav-B Oral Powder**
	Label Claim	Each 100gram Contains: Amoxicillin (as Amoxicillin Trihyderate) USP..... 16gm Clavulanic Acid (as Potastasium Clavulanate) USP..... 4gm Bromhexine HCl BP.....0.5gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2.5kg, 5kg & 10kg - De-Controlled
	Shelf Life (Unit)	2 Year(s)below 25

	For generic drugs (me-too Status)	Amolanic Powder (Reg No. 093846)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	based on the stated observation their current GMP compliance level is rated as Good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	As per letter No. F.2-10/93-Lic (Vol-I) dated 07 June 2022, firm has been granted approval of Dry Powder Sachet (Penicillin) Vet. However, firm has applied for Pack Sizes as 100gm, 250gm, 500gm, 1kg, 2.5kg, 5kg & 10kg with laminated metalized foil pouches and plastic woven bags as proposed container-closure system, Batch Size as 20 KG (20 Bags) and Fill Volume as 1Kg. The said letter suggests that firm has approval only for Sachet. Therefore, firm may be advised to regularize/ obtain requisite approval for the relevant manufacturing section through Licensing Division before the approval of applied formulation. Submitted for consideration of the Board, please.	
	Decision	
	Deferred Deferred for clarification of manufacturing section/ facility from Drug Licensing Division, DRAP.	
968	Case Category	Routine (Sara Mehreen)
	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	(BUM-D1W-76BL, 2025-08-13)
	Detail of Fee Submitted	38700.0, 2025-08-12,
	The proposed proprietary name / brand name	**Neocolimox Powder**
	Label Claim	Each Kg Contains: Amoxicillin as Trihydrate USP.....100gm Colistin Sulphate USP.....50MIU Neomycin Sulphate BP.....200gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100 gm-De-Controlled,2.5 Kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 Degree C in Dry Place
	For generic drugs (me-too Status)	Amcocin Oral Dry Powder by M/s. Selmore Pharmaceuticals (Pvt.) Ltd., (Reg. No.: 083243)
	Pharmacotherapeutic Group of (API)	
	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	
	As per letter No. F.2-10/93-Lic (Vol-I) dated 07 June 2022, firm has been granted approval of Dry Powder Sachet (Penicillin) Vet. However, firm has applied for Pack Sizes as 100gm, 250gm, 500gm, 1kg, 2.5kg, 5kg & 10kg with aluminium sachet (100g), Aluminium Pouch (500g), Plastic Jar (500g) Aluminium Pouch/ plastic jar (1kg) as proposed container-closure system. The said letter suggests that firm has approval only for Sachet. Therefore, firm may be advised to regularize/ obtain requisite approval for the relevant manufacturing section through Licensing Division before the approval of applied formulation. Submitted for consideration of the Board, please.	
	Decision	
	Deferred	

	Deferred for clarification of manufacturing section/ facility from Drug Licensing Division, DRAP.	
969	Case Category	Routine (Sara Mehreen)
	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	(L39-V9X-SBVN, 2026-01-05)
	Detail of Fee Submitted	38700, 2026-01-02,
	The proposed proprietary name / brand name	**DOXYTAL FORTE POWDER**
	Label Claim	Each 100 g Contains: Tylosin Tartrate BP.....20 gm. Doxycycline Hyclate BP.....40 gm.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,100gm-De-Controlled,15 kg-De-Controlled,20 kg-De-Controlled,25 kg-De-Controlled,250gm-De-Controlled,5 kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	TYDOXIN FORTE POWDER (Registration No: 101490) M/S SELMORE PHARMACEUTICALS (pvt) LTD
	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	
970	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	(W36-QAP-EJZL, 2025-10-17)
	Detail of Fee Submitted	37000, 1700 2025-08-06, 2026-07-09
	The proposed proprietary name / brand name	**Star-Spiralin Powder**
	Label Claim	Each 1000gram Contain:- Spiramycin Adipate EP..... 75gm Lincomycin HCL USP.....25gm (Innovaotr'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.
	For generic drugs (me-too Status)	Spirachlor Powder Reg. # 049619
	Pharmacotherapeutic Group of (API)	
	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	
	Evaluation Remarks	
	Decision	
	Approved	
971	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	(DGJ-A9E-A49D, 2025-09-09)
	Detail of Fee Submitted	37000.0, 1700 2025-08-21, 2026-08-03
	The proposed proprietary name / brand name	**Flofenic Powder**
	Label Claim	Each gm contains: Florfenicol .....150 mg Oxytetracycline Hcl BP.... 150 mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,1KG-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C.
	For generic drugs (me-too Status)	Oxy-Floro Water Soluble Powder Reg. # 080726
	Pharmacotherapeutic Group of (API)	
	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	
	Evaluation Remarks	
	Decision	
	Approved	
972	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	(9HQ-DRH-TVAT, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**RENA DINE INJECTION**
	Label Claim	Each ml contains: FUROSEMIDE..... 50mg (USP Specs.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	DURETIC INJECTION. (078208)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
973	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	(H5E-ZJ1-SH85, 2025-12-12)
	Detail of Fee Submitted	37000, 1700 2025-08-06, 2026-07-09
	The proposed proprietary name / brand name	**Tylofos Powder**
	Label Claim	Each Kg contains: Calcium Fosfomycin BP.....200gm Tylosin Tartrate BP.....100gm Fructose USP.....180gm Sodium Phosphate BP.....150gm Magnesium Sulphate BP.....100gm (Innovaotr'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 25o C, Keep away from heat, moisture & children.
	For generic drugs (me-too Status)	Sparkofos Powder Reg. # 112170
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	inspection pennel recommended the renewal of dml and gmp.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
974	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	(AH5-1RW-YBY6, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**QUINE INJECTION**

	Label Claim	Each ml contains Buparvaquone ..... 50mg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20 ml-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	BUPRALEX INJECTION. (033264)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
975	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	(EN3-QJL-Z9A6, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**IMIZOLE INJECTION**
	Label Claim	Each ml contains Imidocarb Dipropionate ..... 120mg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	RED MIDO INJECTION . (063715)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
976	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	(1N1-23W-Z65Y, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**TONOFOS INJECTION**
	Label Claim	Each ml contains Toldimfos Sodium ..... 200mg Vitamin B12 USP.....50mcg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	Tolivetz-B Injection. (102007)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
977	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	(2PP-SBL-HGYZ, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**TONOFOS INJECTION**
	Label Claim	Each ml contains Toldimfos Sodium ..... 200mg Vitamin B12 USP.....50mcg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	Tolivetz-B Injection. (099473)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
978	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	(AHB-91M-2UH7, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**THRUSH- CRD INJECTION**
	Label Claim	Each ml contains:- Tylosin Tartrate BP.....100mg Colistin Sulphate USP.....20mg Streptomycin Sulphate USP...200mg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	CRD Plus Injection. (073934)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
979	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	(BP1-HZ3-8PZP, 2026-02-28)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**THRUSH- CRD INJECTION**
	Label Claim	Each ml contains:- Tylosin Tartrate BP.....100mg Colistin Sulphate USP.....20mg Streptomycin Sulphate USP.....200mg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	CRD Plus Injection. (073934)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
980	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	(UD7-BR7-A53H, 2025-09-08)
	Detail of Fee Submitted	37000.0, 2025-08-12,
	The proposed proprietary name / brand name	**VETEC-AMPROBATE ORAL POWDER**
	Label Claim	Each gram powder contains (Innovator's Spec.) Amprolium HCl USP..... 200mg Ethopabate USP.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-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)Room temperature
	For generic drugs (me-too Status)	ETHOPROL POWDER,Reg no 049617
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GOOD
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
981	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	(P4D-3XE-ML1G, 2025-08-18)
	Detail of Fee Submitted	37000.0, 2025-08-12,
	The proposed proprietary name / brand name	**Vetec-Floxacin liquid**
	Label Claim	Each 100 ml contains Enrofloxacin BP.....20 gm
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,200ml-De-Controlled,2500ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	063619, ENROCK ORAL SOLUTION INTERNATIONALPHARMA LAHORE
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GOOD
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
982	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	(MPX-D4Q-AWA8, 2025-09-21)
	Detail of Fee Submitted	37000, 2025-08-12,
	The proposed proprietary name / brand name	**VETEC-VIRGINIAMIN ORAL POWDER**
	Label Claim	Each gm powder contains Vitamin E BP..... 5mg Vitamin B3 BP.....2mg DL Methionine IP.....50mg Choline chloride USP.....100mg Virginiamycin .....12 mg L Lysine .....25 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-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)Room temperature
	For generic drugs (me-too Status)	Maji Max Oral Water Soluble Powder, Reg No. 089848
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GOOD
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
983	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	(GJA-NBW-R93A, 2025-09-17)
	Detail of Fee Submitted	37000, 2025-08-12,
	The proposed proprietary name / brand name	**Vetec-FurChloride Oral Powder**
	Label Claim	Each 1000gm powder contains (As Per Innovators Spec.) Furosemide (BP)..... 20gm Sodium Chloride(BP).....35gm Magnesium Sulphate(BP).....35gm Manganese Sulphate(BP).....1gm Calcium Carbonate(BP).....45gm Potasium Chloride(BP).....400mg
	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,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	NEPHRALYTE POWDER (071072)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GOOD
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
984	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	(4R5-54S-RP7L, 2025-09-03)
	Detail of Fee Submitted	37000.0, 2025-08-12,
	The proposed proprietary name / brand name	**VETEC-DOXLOSIN ORAL POWDER**
	Label Claim	Each gram contains Doxycycline HCl USP.....200mg Tylosin Tartrate BP..... 100mg Dihydrostreptomycin USP..... 20mg Bromhexine HCl BP..... .....5mg (As per Innovator's Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-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)Room temperature
	For generic drugs (me-too Status)	Doxylo- S Powder, , Reg NO. 075695
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GOOD

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
985	Case Category	Routine (Sara Mehreen)
	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	(87E-TGB-RTJL, 2025-07-26)
	Detail of Fee Submitted	37000.0, 2025-07-24,
	The proposed proprietary name / brand name	**Scour-Stop Oral Solution**
	Label Claim	Each ml Contains: Sulphadiazine BP.....35.5mg Sulphadimidine. BP.....28.4mg Neomycin Sulphate BP.....1.8mg Hyoscine N butylbromide.....0.04mg Pectin USP.....7.1mg Kaolin BP.....103.3mg Vitamin B1 BP.....0.15mg Vitamin B2 BP.....0.22mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 225ml, & 500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)below 30
	For generic drugs (me-too Status)	Scour-X Oral Suspension (Reg No. 029661)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	based on the stated observation their current GMP compliance level is rated as Good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
986	Case Category	Routine (Sara Mehreen)
	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	(TJ2-S4D-L4SU, 2025-08-13)
	Detail of Fee Submitted	38700.0, 2025-08-12,
	The proposed proprietary name / brand name	**Fosboost Powder**
	Label Claim	Each 100gm Contains: Fosfomycin Calcium..... 20gm, Tylosin as Tartrate BP.....10gm, Fructose 1,6 Diphosphate.....18gm, Sodium Phosphate.....15gm, Magnesium Sulphate.....10gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100 gm-De-Controlled,2.5 Kg-De-Controlled,500 gm-De-Controlled

	Shelf Life (Unit)	2 Year(s)Store below 30 Degree C in Dry Place.
	For generic drugs (me-too Status)	Fosfotyl Powder by M/s. Leads Pharma (Pvt.) Ltd. (Reg. No.: 078240)
	Pharmacotherapeutic Group of (API)	
	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	
	As per letter No. F.2-10/93-Lic (Vol-I) dated 07 June 2022, firm has been granted approval of Dry Powder Sachet (Vet). However, firm has applied for Pack Sizes as 100gm, 500gm, 1kg, 2.5kg with aluminum sachet (100g), aluminium pouch (500g, 1kg) and plastic jar (500g,1kg) as proposed container-closure system, Batch Size as 20 KG (20 Bags) and Fill Volume as 1Kg. The said letter suggests that firm has approval only for Sachet. Therefore, firm may be advised to regularize/ obtain requisite approval for the relevant manufacturing section through Licensing Division before the approval of applied formulation. Submitted for consideration of the Board, please.	
	Decision	
	Deferred Deferred from verification by the relevant F.I.D whether the firm has manufacturing facility for Sachet upto 25 Kg.	
987	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**PRIX PHARMACEUTICA (PRIVATE) LIMITED** PLOT NO.5 PHARMACITY, 30-KM MULTAN ROAD, LAHORE **(000587)**
	Application Form Dy. No / Tracking ID & date of submission	(WR2-SAY-X4S2, 2026-03-19)
	Detail of Fee Submitted	38700, 2026-03-12,
	The proposed proprietary name / brand name	**Linco-Spy Injection(Vet) 100ml pack size**
	Label Claim	Each ml injection contains: Siramycin Adipate.....125mg Lincomycin HCl BP---------- 75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 15C ---30C
	For generic drugs (me-too Status)	Lincospira Injection.Reg.#.046570 Pack size 10ml,50ml,100ml
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Authorization of production of medicine in all approved sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
988	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	(1JJ-RPA-5GD2, 2025-08-19)
	Detail of Fee Submitted	37000.0, 2025-08-12,
	The proposed proprietary name / brand name	**Vetec Fossin-20 oral powder**
	Label Claim	Each gm powder contains (Innovator's Spec.) Fosfomycin Calcium BP..... 200mg Tylosin as Tartrate BP.....100mg Fructose 1,6 Diphosphate .....180 mg Sodium Phosphate USP.....150mg Magnesium sulphate 100mg
	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,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	WAL –FOS WATER SOUBLE POWDER (|120736)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GOOD
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
989	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Univet Pharmaceuticals** 14-km adyala Road, Rawalpindi **(000424)**
	Application Form Dy. No / Tracking ID & date of submission	(18W-6JY-VNVB, 2025-11-17)
	Detail of Fee Submitted	38700, 2025-11-11,
	The proposed proprietary name / brand name	**UNI-OXIN LIQUID**
	Label Claim	EACH 1000ml contains: Oxolinic Acid BP.....100gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,250ml,500ml & 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)below 30c
	For generic drugs (me-too Status)	Vety-oxol
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP GRANTED
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
990	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Pinnacle Biotech (Pvt.) Ltd.** FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park,

		Karachi. **(000939)**
	Application Form Dy. No / Tracking ID & date of submission	(D23-MLN-79PE, 2026-03-26)
	Detail of Fee Submitted	38700, 2025-09-26,
	The proposed proprietary name / brand name	**Vasofen 200mg Capsules**
	Label Claim	Each Capsule contains: Fenofibrate (Micronized).... 200mg USP Specs
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's -As per SRO,20's-As per SRO,30's -As per SRO
	Shelf Life (Unit)	2 Year(s)Shelf life only applies under appropriate conditions of storage specified on package.
	For generic drugs (me-too Status)	Fenoget 200mg Capsules by Getz Pharma
	Pharmacotherapeutic Group of (API)	Lipid Modifying Agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	EVEREST ORGANICS LIMITED AROOR VILLAGE SADASIVPET MANDAL SANGAREDDY DISTRICT TELANGANA INDIA
	Detail of stability batches of drug product	stability studies for the Drug Product were conducted under Zone IVa conditions. The stability batch numbers are: T-416, T-417, T418 1000 cap each batch
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 No. of license DIL-C-224909 Issuance Date: 19/03/2024, invoice and GD
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. fenoget 200mg capsule by M/s Getz Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone-IV a
	The status in reference regulatory authorities	Food and Drug Regulatory Authority USA
	GMP status of the firm	67/2024-DRAP (K) 8-5-24 GMP certificate issued on the basis of inspection conducted on 07-05-24 is submitted. Validity: 07-05-2027
	Evidence of approval of manufacturing facility	2-10/2011-LIC 13.08.21 specifying capsule section
	Evaluation Remarks	
	Decision	
	Approved	
991	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Pinnacle Biotech (Pvt.) Ltd.** FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. **(000939)**
	Application Form Dy. No / Tracking ID & date of submission	(H2J-E2Y-AA5Z, 2026-02-24)
	Detail of Fee Submitted	38700, 2025-09-26,
	The proposed proprietary name / brand name	**Vasofen 67mg Capsules**
	Label Claim	Each capsule contains: Fenofibrate Micronized....67mg USP Specs

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Shelf life only applies under appropriate conditions of storage specified on package.
	For generic drugs (me-too Status)	Fenoget 67mg Capsules
	Pharmacotherapeutic Group of (API)	Lipid Modifying Agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	EVEREST ORGANICS LIMITED AROOR VILLAGE SADASIVPET MANDAL SANGAREDDY DISTRICT TELANGANA INDIA
	Detail of stability batches of drug product	stability studies for the Drug Product were conducted under Zone IVa conditions. The stability batch numbers are: T-409, T-410, T411 1000 cap each batch
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 No. of license DIL-C-224909 Issuance Date: 19/03/2024, invoice and GD
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. fenoget 67mg capsule by M/s Getz Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone-IV a
	The status in reference regulatory authorities	Food and Drug Regulatory Authority USA
	GMP status of the firm	67/2024-DRAP (K) 8-5-24 GMP certificate issued on the basis of inspection conducted on 07-05-24 is submitted.
	Evidence of approval of manufacturing facility	2-10/2011-LIC 13.08.21 specifying capsule section
	Evaluation Remarks	
	Decision	
	Approved	
992	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Pinnacle Biotech (Pvt.) Ltd.** FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. **(000939)**
	Application Form Dy. No / Tracking ID & date of submission	(9VA-TGP-7TE3, 2026-03-16)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**Qutiva 25mg Tablet**
	Label Claim	Each film coated tablet contains: Quetiapine fumarate (USP) Equivalent to Quetiapine .....25mg The product complies with USP
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 10's (10Tablets)-As per SRO,2 x10's(20Tablets)-As per SRO,3 x10's(30Tablets)-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 C. Protect from sunlight and moisture. keep out of reach of children.
	For generic drugs (me-too Status)	Qusel 25mg Tablet by Hilton Pharmaceutical

	Pharmacotherapeutic Group of (API)	Antipsychotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Manufacturing Facility: HEMA PHARMACEUTICALS PVT. LTD. Plot No.:-6201/A&B, Opp. Ewac Alloys Ltd., GIDC Estate, Ankleshwar-393002. Gujarat, India.
	Detail of stability batches of drug product	3 batches 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	clearance certificate RO-DEC30 24.02.25
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Qusel 25mg capsule by M/s hilton Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (06 M): 40°C ± 2°C / 75% RH ± 5% & Long term (60 months): 30°C ± 2°C / 65% RH ± 5%
	The status in reference regulatory authorities	Quetiapine Fumarate Tablet By ASTRAZENECA (FDA) https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process& App lNo=020639
	GMP status of the firm	67/2024-DRAP (K) 8-5-24 GMP certificate issued on the basis of inspection conducted on 07-05-24 is submitted.
	Evidence of approval of manufacturing facility	2-10/2011-LIC 13.08.21 specifying tablet section
	Evaluation Remarks	
	Decision	
	Approved	
993	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Pinnacle Biotech (Pvt.) Ltd.** FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. **(000939)**
	Application Form Dy. No / Tracking ID & date of submission	(Q5S-BET-MXHT, 2026-03-31)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**Qutiva 100mg Tablet**
	Label Claim	Each Film Coated tablet contains: Quetiapine Fumarate (USP) equivalent to Quetiapine.....100mg The product complies with USP
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's (10Tablets)-As per SRO,2x10's (20Tablets)-As per SRO,3x10's(30Tablets)-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 C. Protect from sunlight and moisture. keep out of reach of children.
	For generic drugs (me-too Status)	Quetiapine Fumerate 100mg Tablet
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Manufacturing Facility: HEMA PHARMACEUTICALS PVT. LTD. Plot No.:-

		6201/A&B, Opp. Ewac Alloys Ltd., GIDC Estate, Ankleshwar-393002. Gujarat, India.
	Detail of stability batches of drug product	3 batches 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	clearance certificate RO-DEC30 24.02.25
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Qusel 100mg capsule by M/s hilton Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (06): 40°C ± 2°C / 75% RH ± 5% & Long term (60 months): 30°C ± 2°C / 65% RH ± 5%
	The status in reference regulatory authorities	Quetiapine Fumarate manufactured by ASTRAZENECA (FDA)https://www.accessdata.fda.gov/scripts/cder event=overview.process& App lNo=020639
	GMP status of the firm	67/2024-DRAP (K) 8-5-24 GMP certificate issued on the basis of inspection conducted on 07-05-24 is submitted.
	Evidence of approval of manufacturing facility	2-10/2011-LIC 13.08.21 specifying tablet section
	Evaluation Remarks	
	Decision	
	Approved	
994	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Pinnacle Biotech (Pvt.) Ltd.** FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. **(000939)**
	Application Form Dy. No / Tracking ID & date of submission	(A7L-N3Z-L61Q, 2026-03-17)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**Qutiva 200mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Quetiapine Fumarate (USP) equivalent to Quetiapine.....200mg The product complies with USP
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's (10Tablets) -As per SRO,2 x10's (20Tablets)-As per SRO,3 x10's (30Tablets)-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 C. Protect from sunlight and moisture. keep out of reach of children.
	For generic drugs (me-too Status)	Quetiapine Fumerate 200mg Tablet
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Manufacturing Facility: HEMA PHARMACEUTICALS PVT. LTD. Plot No.:-6201/A&B, Opp. Ewac Alloys Ltd., GIDC Estate, Ankleshwar-393002. Gujarat, India.
	Detail of stability batches of drug product	3 batches 1500 tablets each
	Documents for the procurement of API with approval from DRAP	clearance certificate RO-DEC30 24.02.25

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Qusel 200mg capsule by M/s hilton Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (06): 40°C ± 2°C / 75% RH ± 5% & Long term (60 months): 30°C ± 2°C / 65% RH ± 5%
	The status in reference regulatory authorities	Quetiapine Fumarate manufactured by ASTRAZENECA (FDA)https://www.accessdata.fda.gov/scripts/cder event=overview.process& App lNo=020639
	GMP status of the firm	67/2024-DRAP (K) 8-5-24 GMP certificate issued on the basis of inspection conducted on 07-05-24 is submitted.
	Evidence of approval of manufacturing facility	2-10/2011-LIC 13.08.21 specifying tablet section
	Evaluation Remarks	
	Decision	
	Approved	
995	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Pinnacle Biotech (Pvt.) Ltd.** FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. **(000939)**
	Application Form Dy. No / Tracking ID & date of submission	(SM5-2GX-286B, 2026-03-09)
	Detail of Fee Submitted	38700, 38700 2025-10-06, 2026-02-26
	The proposed proprietary name / brand name	**Pinnaxam 250mg Capsule**
	Label Claim	Each Capsule contains: Tranexamic acid (USP).....250mg. The Product complies with JP.
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	100's-As per SRO,1x10's -As per SRO,2x10's-As per SRO,3x10's -As per SRO,50's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 C. Protect from sunlight and moisture. keep out of reach of children.
	For generic drugs (me-too Status)	Transamin 250mg Capsule by Hilton Pharma
	Pharmacotherapeutic Group of (API)	Antihemorrhagics/ Antifibrinolytic Agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SHILPA PHARMA LIFESCIENCES LIMITED. Address: Shilpa House, #12-6-214/A1, Hyderabad Road,Raichur – 584 135, Karnataka, India.
	Detail of stability batches of drug product	3 batches 1000 cap each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 No. of license DIL-C-7DCA0C Issuance Date 06/12/2024, invoice and GD Clearance certificate ROOECD9C
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. transamin 250mg capsule by M/s hilton Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (06): 40°C ± 2°C / 75% RH ± 5% & Long term (60 months): 25°C ± 2°C / 60% RH ± 5%

	The status in reference regulatory authorities	Tranexamic Acid Capsule by Daiichi Sankyo Company, Limited (Japan). https://www.pmda.go.jp/files/000153314.pdf
	GMP status of the firm	67/2024-DRAP (K) 8-5-24 GMP certificate issued on the basis of inspection conducted on 07-05-24 is submitted.
	Evidence of approval of manufacturing facility	2-10/2011-LIC 13.08.21 specifying capsule section
	Evaluation Remarks	
	Decision	
	Approved	
996	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Pinnacle Biotech (Pvt.) Ltd.** FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. **(000939)**
	Application Form Dy. No / Tracking ID & date of submission	(1XM-AAH-J8M5, 2026-02-19)
	Detail of Fee Submitted	38700, 2025-10-06,
	The proposed proprietary name / brand name	**Pinnaxam 500mg Capsule**
	Label Claim	Each Capsule contains: Tranexamic acid (USP).....500mg The product complies with JP.
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	100's -As per SRO,1x10's -As per SRO,2x10's-As per SRO,3x10's -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 C. Protect from sunlight and moisture. keep out of reach of children.
	For generic drugs (me-too Status)	Transamin 500mg Capsule by Hilton Pharma
	Pharmacotherapeutic Group of (API)	Antihemorrhagics/ Antifibrinolytic Agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SHILPA PHARMA LIFESCIENCES LIMITED. Address: Shilpa House, #12-6-214/A1, Hyderabad Road, Raichur – 584 135, Karnataka, India.
	Detail of stability batches of drug product	3 batches 1000 cap each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 No. of license DIL-C-7DCA0C Issuance Date 06/12/2024, invoice and GD Clearance certificate ROOECD9C
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. transamin 500mg capsule by M/s hilton Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (06): 40°C ± 2°C / 75% RH ± 5% & Long term (60 months): 25°C ± 2°C / 60% RH ± 5%
	The status in reference regulatory authorities	Tranexamic Acid Capsule by Daiichi Sankyo Company, Limited (Japan). https://www.pmda.go.jp/files/000153314.pdf
	GMP status of the firm	67/2024-DRAP (K) 8-5-24 GMP certificate issued on the basis of inspection conducted on 07-05-24 is submitted.
	Evidence of approval of manufacturing facility	2-10/2011-LIC 13.08.21 specifying capsule section

	Evaluation Remarks	
	Decision	
	Approved	
997	Case Category	Contract Manufacturing (Shahrukh Ali)
	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	(HQ9-4EX-ULEJ, 2024-08-20)
	Detail of Fee Submitted	75000.0, 2024-06-26,
	The proposed proprietary name / brand name	**Methyll 125mg Injection**
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....125mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C.
	For generic drugs (me-too Status)	Solu Medrol injection by Pfizer
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-Plot No. 31 & 32, Punjab Small Industrial Estate, Taxila, Rawalpindi-
	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	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
998	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)**
	Application Form Dy. No / Tracking ID & date of submission	(4DH-V8G-DXGV, 2025-04-14)

	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	**Unicef 400mg tablet**
	Label Claim	Each film coated tablet contains: Cefixime trihydrate eq to cefixime....400mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,12's-As per SRO,14's-As per SRO,20's-As per SRO,30's-As per SRO,40's-As per SRO,6's-As per SRO,7'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)	Liskoxime 400mg Tablet, manufactured by Lisko Pakistan (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Antibiotics (Cephalosporin)
	Name, address of Manufacturing site:	Platinum Pharmaceuticals (Pvt) Ltd-Plot no. A-20, North Western Industrial Zone, Bin Qasim Authority, Karachi-75020, Pakistan-
	Name & address of API manufacturer	Citi Pharma, Address 3 Kilometer, Head Bal- loki Road, Phool Na- gar, Kasur -55050 Pun- jab, Pakistan.
	Detail of stability batches of drug product	1000 tablet 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	locally purchased
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cebosch 400 mg tablets manufactured by Getz pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Medicines & Healthcare products regulatory Agency (MHRA)
	GMP status of the firm	Certificate no 46/2023-DRAP (K) dated 16-06-23 Platinum contract acceptor
	Evidence of approval of manufacturing facility	No F.2-3/94(Vol-III)-Lic dated 16-11-22 mentioning tablet cephalosporin section
	Evaluation Remarks	
	Decision	
	Approved	
999	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)**
	Application Form Dy. No / Tracking ID & date of submission	(8GJ-DTX-7MA5, 2025-04-15)
	Detail of Fee Submitted	93000.0, 2025-01-15,
	The proposed proprietary name / brand name	**Unicef 200mg tablet**
	Label Claim	Each film coated tablet contains:- Cefixime trihydrate eq. to cefixime.....200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,12's-As per SRO,14's-As per SRO,20's-As per SRO,30's-As per SRO,40's-As per SRO,6's-As per SRO,7'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)	Fixicef 200mg Table, manufactured by Opal Laboratories (Pvt) Ltd. LC/41 SITE Landhi Karachi. Pakistan
	Pharmacotherapeutic Group of (API)	Antibiotics (Cephalosporin)
	Name, address of Manufacturing site:	Platinum Pharmaceuticals (Pvt) Ltd-Plot no. A-20, North Western Industrial Zone, Bin Qasim Authority, Karachi-75020, Pakistan-
	Name & address of API manufacturer	Pharmagen Limited, Address Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Detail of stability batches of drug product	1000 tablet 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	locally purchased
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefiget 200 mg tablets manufactured by Getz pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Medicines & Healthcare products regulatory Agency (MHRA)
	GMP status of the firm	Certificate no 46/2023-DRAP (K) dated 16-06-23 Platinum contract acceptor
	Evidence of approval of manufacturing facility	No F.2-3/94(Vol-III)-Lic dated 16-11-22 mentioning tablet cephalosporin section
	Evaluation Remarks	
	Decision	
	Approved	
1000	Case Category	Contract Manufacturing (Shahrukh Ali)
	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	(PRD-VXP-82RW, 2024-09-30)
	Detail of Fee Submitted	93000.0, 9400 2024-09-21, 2026-07-30
	The proposed proprietary name / brand name	**FLUCAS 50mcg Nasal Drops**
	Label Claim	Each Spray Contains: Fluticasone Propionate (USP).....50mcg (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)	Flexosone Nasal Spray Each actuation contains:- Fluticasone Propionate BP ……..50ug Reg No. 040863 Schazoo Laboratories
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Winbrains Research Laboratories, -Plot no. 69/1, Block B, Phase I & II, 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	https://www.accessdata.fda.gov/drugsatfda_docs/l
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
1001	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	(ZM4-273-EDL6, 2025-02-13)
	Detail of Fee Submitted	37000.0, 2024-10-31,
	The proposed proprietary name / brand name	**Cefraxis Capsule 500mg**
	Label Claim	Each capsule contains: Cefradine(as monohydrate).....500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	12's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Velosef Capsule 500mg
	Pharmacotherapeutic Group of (API)	Antiinfective for systemic use (3rd generation cephalosporins)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pharmagen Limited
	Detail of stability batches of drug product	3 Batch manufactured each having 1000 cap batch sizes
	Documents for the procurement of API with approval from DRAP (in case of Import)	locally purchased from pharmagen
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Velosef Capsule 500mg of GSK Pakistan Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 Batches of API As per Zone IV-A
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 3-7-2024

	Evidence of approval of manufacturing facility	letter for issurance of Cephalosporins section approval dated 23-08-2024
	Evaluation Remarks	
	Decision	
	Approved	
1002	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	(MS7-SDD-PPVN, 2025-03-11)
	Detail of Fee Submitted	37000.0, 2024-10-31,
	The proposed proprietary name / brand name	**Cefraxis Capsule 250mg**
	Label Claim	Each Capsule contains: Cefradine(as monohydrate).....250mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	12's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Velosef Capsule 250mg
	Pharmacotherapeutic Group of (API)	Antiinfective for systemic use (3rd generation cephalosporins)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pharmagen Limited
	Detail of stability batches of drug product	3 Batch manufactured each having 1000 cap batch sizes
	Documents for the procurement of API with approval from DRAP (in case of Import)	locally purchased from ms pharmagen
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Velosef Capsule 250mg of GSK Pakistan Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 Batches of API As per Zone IV-A
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 3-7-2024
	Evidence of approval of manufacturing facility	letter for issurance of Cephalosporins section approval dated 23-08-2024
	Evaluation Remarks	
	Decision	
	Approved	
1003	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	(PWH-GPJ-DP7G, 2025-03-11)
	Detail of Fee Submitted	37000.0, 2024-11-12,

	The proposed proprietary name / brand name	**Cefraxis Dry Suspension250mg/5ml**
	Label Claim	Each 5ml (after reconstitution) contains: Cefradine(as monohydrate).....250mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Velosef Dry Suspension250mg/5ml
	Pharmacotherapeutic Group of (API)	Antiinfective for systemic use (3rd generation cephalosporins)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pharmagen Limited
	Detail of stability batches of drug product	3 batches 50 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	locally purchased from pharmagen
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Velosef Dry Suspension250mg/5ml of GSK Pakistan Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 Batches of API As per Zone IV-A
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 3-7-2024
	Evidence of approval of manufacturing facility	letter for issurance of Cephalosporins section approval dated 23-08-2024
	Evaluation Remarks	
	Decision	
	Approved	
1004	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)**
	Application Form Dy. No / Tracking ID & date of submission	(BU6-D5N-NZ6U, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2024-09-18,
	The proposed proprietary name / brand name	**Unicef 100mg/5ml powder for suspension**
	Label Claim	Each 5 ml of reconstituted suspension contains: Cefixime trihydrate equivalent to cefixime.... 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30 ml-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)	Cefspan 100mg/5ml powder for oral suspension Manufacturer: Barrett Hodsgon pakistan (pvt) ltd
	Pharmacotherapeutic Group of (API)	Antibiotics (Cephalosporin)
	Name, address of Manufacturing site:	Platinum Pharmaceuticals (Pvt) Ltd.,-E-127/E-128/E-129, NORTH WESTERN INDUSTRIAL ZONE, PORT QASIM, Malir Bin Qaism Town-
	Name & address of API manufacturer	Pharmagen Limited Address: Kot Nabi Bukshwala, 34 Km Ferozepur Road, La- hore.

	Detail of stability batches of drug product	200kg 3 batches 24 months real time and 6 month accelerated study
	Documents for the procurement of API with approval from DRAP (in case of Import)	locally purchased
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefspan 100mg/5ml powder for oral suspension Manufacturer: Barrett Hodsgon pakistan (pvt) ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Italian medicines Agency (AIFA)
	GMP status of the firm	Certificate no 46/2023-DRAP (K) dated 16-06-23 Platinum contract acceptor
	Evidence of approval of manufacturing facility	No F.2-3/94(Vol-III)-Lic dated 16-11-22 cephalosporin section
	Evaluation Remarks	
	Decision	
	Approved	
1005	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)**
	Application Form Dy. No / Tracking ID & date of submission	(WZT-TZB-8BE4, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2024-09-18,
	The proposed proprietary name / brand name	**Unicef 200mg/5ml powder for suspension**
	Label Claim	Each 5 ml of reconstituted suspension contains: Cefixime trihydrate, equivalent to cefixime....200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-As per SRO,25ml-As per SRO,30ml-As per SRO,50ml-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)	Cefspan 200mg/5ml powder for suspension Company:Barrett Hodgson Pakistan (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Antibiotics (Cephalosporin)
	Name, address of Manufacturing site:	Platinum Pharmaceuticals (Pvt) Ltd.,-E-127/E-128/E-129, NORTH WESTERN INDUSTRIAL ZONE, PORT QASIM, Malir Bin Qaism Town-
	Name & address of API manufacturer	Pharmagen Limited Address: Kot Nabi Bukshwala, 34 Km Ferozepur Road, La- hore.
	Detail of stability batches of drug product	200kg 3 batches 24 months real time and 6 month accelerated study
	Documents for the procurement of API with approval from DRAP (in case of Import)	locally purchased
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefspan 200mg/5ml powder for suspension Company:Barrett Hodgson Pakistan (Pvt) Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Food and Drug Administration (FDA) USA

	GMP status of the firm	Certificate no 46/2023-DRAP (K) dated 16-06-23 Platinum contract acceptor
	Evidence of approval of manufacturing facility	No F.2-3/94(Vol-III)-Lic dated 16-11-22 cephalosporin section
	Evaluation Remarks	
	Decision	
	Approved	
1006	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)**
	Application Form Dy. No / Tracking ID & date of submission	(L7W-Z4P-T8N7, 2025-05-13)
	Detail of Fee Submitted	93000.0, 2024-09-18,
	The proposed proprietary name / brand name	**Unicef 200mg capsule**
	Label Claim	Each hard gelatin capsule contains: Cefixime (as trihydrate).....200mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	14's-As per SRO,21's-As per SRO,5's-As per SRO
	Shelf Life (Unit)	3 Year(s)store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Cefix Capsule 200mg, manufactured by Standpharm Pakistan (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Antibiotics (Cephalosporin)
	Name, address of Manufacturing site:	Platinum Pharmaceuticals (Pvt) Ltd-Plot no. A-20, North Western Industrial Zone, Bin Qasim Authority, Karachi-75020, Pakistan-
	Name & address of API manufacturer	Pharmagen Limited, Address Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Detail of stability batches of drug product	1000 capsule 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	locally purchased
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefix Capsule 200mg, manufactured by Standpharm Pakistan (Pvt) Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	The Spanish Agency of Medicines and Medical Devices(cima)
	GMP status of the firm	Certificate no 46/2023-DRAP (K) dated 16-06-23 Platinum contract acceptor
	Evidence of approval of manufacturing facility	No F.2-3/94(Vol-III)-Lic dated 16-11-22 mentioning capsule cephalosporin section
	Evaluation Remarks	
	Decision	
	Approved	
1007	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port

		Qasim Authority, Karachi **(000755)**
	Application Form Dy. No / Tracking ID & date of submission	(5GT-H1L-ZGNW, 2025-04-14)
	Detail of Fee Submitted	93000.0, 2024-09-18,
	The proposed proprietary name / brand name	**Unicef 400mg capsule**
	Label Claim	Each hard Gelatin capsule Contains: Cefixime as Trihydrate.....400mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	5's-As per SRO,6's-As per SRO
	Shelf Life (Unit)	3 Year(s)store below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Cefim Capsule 400mg manufactured by Hilton Pharma (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Antibiotics (Cephalosporin)
	Name, address of Manufacturing site:	Platinum Pharmaceuticals (Pvt) Ltd-Plot no. A-20, North Western Industrial Zone, Bin Qasim Authority, Karachi-75020, Pakistan-
	Name & address of API manufacturer	Pharmagen Limited, Address Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Detail of stability batches of drug product	50000 capsule batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	locally purchased
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefim Capsule 400mg manufactured by Hilton Pharma (Pvt) Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Food & Drug administration (FDA)
	GMP status of the firm	Certificate no 46/2023-DRAP (K) dated 16-06-23 Platinum contract acceptor
	Evidence of approval of manufacturing facility	No F.2-3/94(Vol-III)-Lic dated 16-11-22 mentioning capsule cephalosporin section
	Evaluation Remarks	
	Decision	
	Approved	
1008	Case Category	Routine (Shahrukh Ali)
	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	(R9Z-DRD-6BDE, 2025-05-12)
	Detail of Fee Submitted	37000.0, 2025-02-28,
	The proposed proprietary name / brand name	**Ceftas Tablet 200mg**
	Label Claim	Each film coated tablet contains:- Cefixime trihydrate eq. to cefixime.....200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-As per SRO,1x5's-As per SRO,2x5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 C
	For generic drugs (me-too Status)	SAMI PHARMACEUTICALS PRIVATE LIMITED

	Pharmacotherapeutic Group of (API)	Antibiotics (Cephalosporin)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	PHARMAGEN PRIVATE LIMITED
	Detail of stability batches of drug product	1000 tablet 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	locally purchased
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefiget 200 mg tablets manufactured by Getz pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	Certificate no 46/2023-DRAP (K) dated 16-06-23
	Evidence of approval of manufacturing facility	No F.2-3/94(Vol-III)-Lic dated 16-11-22 mentioning tablet cephalosporin section
	Evaluation Remarks	
	Decision	
	Approved	
1009	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**TRISON RESEARCH LABORATORIES PRIVATE LIMITED** 27-A PUNJAB SMALL INDUSTRIAL ESTATE **(000529)**
	Application Form Dy. No / Tracking ID & date of submission	(4QA-JUS-X3QA, 2025-06-16)
	Detail of Fee Submitted	93000.0, 9400 2024-09-23, 2026-08-03
	The proposed proprietary name / brand name	**Penxime 400mg Capsule**
	Label Claim	Penxime Capsule 400mg Each capsule contains: Cefixime (as trihydrate) .....400mg Manufacturer Specification
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	5-As per SRO
	Shelf Life (Unit)	2 YearStore at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Cefiget 400mg Capsule (Opal Lab. Karachi) Reg. No. 045118)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Synchro Pharmaceuticals -77-Industrial Estate Kot Lakhpath Lahore-
	Name & address of API manufacturer	Citi Pharma
	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	Suprax 400mg Capsule (USFDA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV vide B5L-DBP-7WSW dated 21-May, 2025.	
	Decision	
	Approved	
1010	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(EHQ-P7P-X8MW, 2025-02-11)
	Detail of Fee Submitted	75000.0, 18000.0 2024-05-24, 2024-10-21
	The proposed proprietary name / brand name	**Zevxime 400mg Capsule**
	Label Claim	Each capsule contains: Cefixime as trihydrate.....400mg (Manufacturer's Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	Evofix Capsule 400mg (Reg No. 029151) Manufactured by PharmEvo Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	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	Suprax Capsule 400mg (USFDA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
1011	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(WWB-8SJ-B344, 2025-04-05)
	Detail of Fee Submitted	75000.0, 18000.0 2024-05-24, 2024-10-21
	The proposed proprietary name / brand name	**Zevxime 100mg/5mL Powder for Oral Suspension**
	Label Claim	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate.....100mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	Evofix Suspension 100mg (Reg No. 029152) Manufactured by PharmEvo Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	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	Suprax Suspension 100mg (USFDA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
1012	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(E3R-83T-N77E, 2024-06-26)
	Detail of Fee Submitted	, ,
	The proposed proprietary name / brand name	**SARGLIP Tablet**

	Label Claim	Each Film Coated Tablet containing: Trelagliptin Succinate eq. to 50mg of Trelagliptin.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Trelaget Tablet (Getz Pharma.)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	Name & address of API manufacturer	M/s Anhui Haikang Pharmaceutical Co., Ltd., No. 21 Huancheng West Road Anqing Anhui 246000 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	Zafate (Teijin Pharma Ltd.) Approved in PMDA Japan.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The data submitted in the present application, including CDP, AMV, stability studies, chromatograms (same file name, retention time, peak area, date and time), and other analytical records, are identical to those submitted by another applicant in application Q7R-63Y-GT2E.	
	Decision	
	Rejected The data submitted in the present application, including CDP, AMV, stability studies, chromatograms (same file name, retention time, peak area, date and time), and other analytical records, are identical to those submitted by another applicant in application Q7R-63Y-GT2E.	
1013	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(5B2-RL2-LWLL, 2024-06-28)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	**TRISEPT**
	Label Claim	Each Film Coated Tablet contains: Trelagliptin Succinate eq. to Trelagliptin.....100mg (Innovator specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	TRELAGET TABLET BY GETZ PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-

	Name & address of API manufacturer	Anhui Haikang Pharmaceutical Co., Ltd.,No. 21 Huancheng West Road Anqing Anhui 246000 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	ZAFATEC TABLET BY TEIJIN PHARMA LTD.Japan
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The data submitted in the present application, including CDP, AMV, stability studies, chromatograms (same file name, retention time, peak area, date and time), and other analytical records, are identical to those submitted by another applicant in application U2Y-7NY-DSLZ.	
	Decision	
	Rejected The data submitted in the present application, including CDP, AMV, stability studies, chromatograms (same file name, retention time, peak area, date and time), and other analytical records, are identical to those submitted by another applicant in application U2Y-7NY-DSLZ.	
1014	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(YTQ-UMW-9LH1, 2024-06-24)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	**Trisept**
	Label Claim	Each film coated tablet contains: Trelagliptin succinate eq. to Trelagliptin.....50mg (Innovator specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	TRELAGET TABLET BY GETZ PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	Name & address of API manufacturer	Anhui Haikang Pharmaceutical Co., Ltd No. 21 Huancheng West Road Anqing Anhui 246000 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	ZAFATEC TABLET BY TEIJIN PHARMA LTD.,Japan
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The data submitted in the present application, including CDP, AMV, stability studies, chromatograms (same file name, retention time, peak area, date and time), and other analytical records, are identical to those submitted by another applicant in application Q7R-63Y-GT2E.	
	Decision	
	Rejected The data submitted in the present application, including CDP, AMV, stability studies, chromatograms (same file name, retention time, peak area, date and time), and other analytical records, are identical to those submitted by another applicant in application Q7R-63Y-GT2E.	
1015	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(UY7-MB4-W2X5, 2025-05-12)
	Detail of Fee Submitted	93000.0, 9400 2024-09-09, 2026-08-12
	The proposed proprietary name / brand name	**Cefno Injection 2gm**
	Label Claim	Each vial contains: Cefoperazone Sodium eq. to Cefoperazone.....1000mg + Sulbactam Sodium eq. to Sulbactam.....1000mg (Japanese Pharmacopeai)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	Sulzone 2 gm Injection (Manufactured by Biocare Pharmaceutica Lahore) Reg No. 028467
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	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	Cefobid Injection 2gm (Manufactured by Pfizer Pvt. Ltd.) FDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the	

	Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
1016	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(JZ8-EUS-HPUD, 2025-04-05)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-15, 2024-10-09
	The proposed proprietary name / brand name	**Cefto 500mg Injection IM**
	Label Claim	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone.....500mg (USP Specifications)
	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)	Rocephin Injection 500mg (Manufactured by Martin Dow Pvt. Ltd)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	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	Ceftriaxone for Injection 500mg USP (Manufactured by Sandoz Pvt. Ltd.)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV vide AX6-XZ6-VWHR dated 21-april, 2026.	
	Decision	
	Approved	
1017	Case Category	Routine (Shahrukh Ali)

	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	(NA5-6BR-4MM3, 2024-10-21)
	Detail of Fee Submitted	37000.0, 2024-10-18,
	The proposed proprietary name / brand name	**APRIM 30MG Tablet**
	Label Claim	Each Film Coated Tablet contains: Apremilast.....30mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	Aprast Tablet by Genix Pharma
	Pharmacotherapeutic Group of (API)	Anti-Psoriatic (PDE 4 Inhibitor) WHO ATC code: L04AA32
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 Batches Size 1200 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	DIL-C-23C215 17.04.24
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Otezla 30mg tablets,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	UK MHRA Approved
	GMP status of the firm	GMP/C/000064/82026 11.8.26
	Evidence of approval of manufacturing facility	No F.3-8/2007-Lic(vol-I) dated 11-10-2008 mentioning Tablet section
	Evaluation Remarks	
	The Presentation of Unit Carton is of 14 Days Starter Pack and 28 Days Starter pack detail of which is as below. A unit carton of 14 days starter pack shall contains:Pouch-I: 1 blister of 4 tablets containing apremilast 10mg.Pouch-II: 1 blister of 4 tablets containing apremilast 20mg.Pouch-III: 2 blisters of 19 tablets containing apremilast 30mg (1 blister with 5 tablets and1 blister with 14 tablets). A unit carton of 28 days starter pack shall contain:Pouch-I: 1 blister of 4 tablets containing apremilast 10mg.Pouch-II: 1 blister of 4 tablets containing apremilast 20mg.Pouch-III: 4 blisters of 47 tablets containing apremilast 30mg (1 blister with 5 tablets and3 blisters with 14 tablets each).	
	Decision	
	Approved	
1018	Case Category	Routine (Shahrukh Ali)
	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	(XDS-2NJ-SQJ5, 2024-10-21)
	Detail of Fee Submitted	37000.0, 2024-10-18,
	The proposed proprietary name / brand name	**APRIM 10MG Tablet**
	Label Claim	Each Film Coated Tablet contains: Apremilast.....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 below 25°c
	For generic drugs (me-too Status)	Aprast Tablet by Genix Pharma
	Pharmacotherapeutic Group of (API)	Anti-Psoriatic (PDE 4 Inhibitor) WHO ATC code: L04AA32
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 Batches Size 1200 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	DIL-C-23C215 17.04.24
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Otezla 10mg tablets,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	UK MHRA Approved
	GMP status of the firm	GMP/C/000064/82026 11.8.26
	Evidence of approval of manufacturing facility	No F.3-8/2007-Lic(vol-I) dated 11-10-2008 mentioning Tablet section
	Evaluation Remarks	
	The Presentation of Unit Carton is of 14 Days Starter Pack and 28 Days Starter pack detail of which is as below. A unit carton of 14 days starter pack shall contains:Pouch-I: 1 blister of 4 tablets containing apremilast 10mg.Pouch-II: 1 blister of 4 tablets containing apremilast 20mg.Pouch-III: 2 blisters of 19 tablets containing apremilast 30mg (1 blister with 5 tablets and1 blister with 14 tablets). A unit carton of 28 days starter pack shall contain:Pouch-I: 1 blister of 4 tablets containing apremilast 10mg.Pouch-II: 1 blister of 4 tablets containing apremilast 20mg.Pouch-III: 4 blisters of 47 tablets containing apremilast 30mg (1 blister with 5 tablets and3 blisters with 14 tablets each).	
	Decision	
	Approved	
1019	Case Category	Routine (Shahrukh Ali)
	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	(WRA-ZSZ-PHM8, 2024-10-21)
	Detail of Fee Submitted	37000.0, 2024-10-18,
	The proposed proprietary name / brand name	**APRIM 20MG Tablet**
	Label Claim	Each Film Coated Tablet contains: Apremilast.....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 Year(s)Store below 25°c
	For generic drugs (me-too Status)	Aprast Tablet by Genix Pharma
	Pharmacotherapeutic Group of (API)	Anti-Psoriatic (PDE 4 Inhibitor) WHO ATC code: L04AA32
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	

	Detail of stability batches of drug product	3 Batches Size 1200 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	DIL-C-23C215 17.04.24
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Otezla 20mg tablets,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	UK MHRA Approved
	GMP status of the firm	GMP/C/000064/82026 11.8.26
	Evidence of approval of manufacturing facility	No F.3-8/2007-Lic(vol-I) dated 11-10-2008 mentioning Tablet section
	Evaluation Remarks	
	A unit carton of 14 days starter pack shall contains:Pouch-I: 1 blister of 4 tablets containing apremilast 10mg.Pouch-II: 1 blister of 4 tablets containing apremilast 20mg.Pouch-III: 2 blisters of 19 tablets containing apremilast 30mg (1 blister with 5 tablets and1 blister with 14 tablets). A unit carton of 28 days starter pack shall contain:Pouch-I: 1 blister of 4 tablets containing apremilast 10mg.Pouch-II: 1 blister of 4 tablets containing apremilast 20mg.Pouch-III: 4 blisters of 47 tablets containing apremilast 30mg (1 blister with 5 tablets and3 blisters with 14 tablets each).	
	Decision	
	Approved	
1020	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)**
	Application Form Dy. No / Tracking ID & date of submission	(JND-149-HT4D, 2025-05-13)
	Detail of Fee Submitted	93000.0, 2025-02-19,
	The proposed proprietary name / brand name	**CEFACT 250mg/5ml**
	Label Claim	Each 5 ml of reconstituted suspension contains: Cefadroxil as monohydrate.....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-As per SRO,50ml-As per SRO,60ml-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)	Oroxizaf 250mg/ml Oral Dry Suspension, Manufactured by: Zafa Pharmaceutical Lab (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Antibacterial (1st generation Cephalosporin)
	Name, address of Manufacturing site:	Platinum Pharmaceuticals (Pvt) Ltd.,-Plot no. A-20, North Western Industrial Zone, Bin Qasim Authority, Karachi-75020, Pakistan.-
	Name & address of API manufacturer	Pharmagen Limited. ADDRESS: 34-Km, Ferozepur Road, Lahore, Pakistan
	Detail of stability batches of drug product	15000 packs 3 batches Accelerated Stability Study {0, 3, 6 months (completed)}, Long term / Real time stability study{3, 6,9,12,18 & 24 months (completed)}
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not applicable since the material is not imported & the API is procured from the local source

		Pharmagen Limited. ADDRESS: 34-Km, Ferozepur Road, Lahore, Pakistan
	Pharmaceutical Equivalence and Comparative Dissolution Profile	pharmaceutical equivalence provided, Duricef 250mg/5ml M/s Gsk
	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	Food & Drug Administration (FDA)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 3-7-2024
	Evidence of approval of manufacturing facility	letter for issurance of Cephalosporins section approval dated 23-08-2024
	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	
1021	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)**
	Application Form Dy. No / Tracking ID & date of submission	(DGT-9E3-5B93, 2025-05-13)
	Detail of Fee Submitted	93000.0, 2025-02-19,
	The proposed proprietary name / brand name	**CEFACT 125mg/5ml oral dry suspension**
	Label Claim	Each 5 ml of reconstituted suspension contains: Cefadroxil as monohydrate.....125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100's-As per SRO,60ml-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)	Oroxizaf 125mg/ml Oral Dry Suspension, Manufactured by: Zafa Pharmaceutical Lab (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Antibacterial (1st generation Cephalosporin)
	Name, address of Manufacturing site:	Platinum Pharmaceuticals (Pvt) Ltd.,-Plot no. A-20, North Western Industrial Zone, Bin Qasim Authority, Karachi-75020, Pakistan.-
	Name & address of API manufacturer	Pharmagen Limited. ADDRESS: 34-Km, Ferozepur Road, Lahore, Pakistan
	Detail of stability batches of drug product	Accelerated Stability Study {0, 3, 6 months (completed)}, Long term / Real time stability study{0,3, 6,9,12,18 & 24 months (completed)}
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not applicable since the material is not imported & the API is procured from the local source Pharmagen Limited. ADDRESS: 34-Km, Ferozepur Road, Lahore, Pakistan

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Oroxizaf 125mg/ml Oral Dry Suspension, Manufactured by: Zafa Pharmaceutical Lab (Pvt) Ltd of GSK Pakistan Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 Batches of API As per Zone IV-A
	The status in reference regulatory authorities	French National Agency for Medicines and Health Prod- ucts Safety (ANSM)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 3-7-2024
	Evidence of approval of manufacturing facility	letter for issurance of Cephalosporins section approval dated 23-08-2024
	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	
1022	Case Category	New Molecule/Formulation (Shahrukh Ali)
	Name, address of Applicant.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)**
	Application Form Dy. No / Tracking ID & date of submission	(H8D-211-18X4, 2025-05-13)
	Detail of Fee Submitted	75000.0, 2025-02-03,
	The proposed proprietary name / brand name	**OLAPIN 5MG TABLET**
	Label Claim	Each Film Coated Tablet Contains: Olopatadine Hydrochloride 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,100's-As per SRO,20's-As per SRO,50'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)	Not applicable since its a new drug product
	Pharmacotherapeutic Group of (API)	Selective Histamine H1-Receptor Antagonist (ATC code: S01GX09)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Micro Orgo-Chem. address: C-1/ B, 57, LIC SECTOR, G.I.D.C.VAPI - 396 195 DlST.- Valsad INDIA
	Detail of stability batches of drug product	3 batches Batch Size 1000 tablet
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: K-1997646088216 Date of issue: 14-Jun-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Allelock tablet "kyowao hakko kirin pharmaceutical"
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A

	The status in reference regulatory authorities	Pharmaceuticals and Medical Devices Agency (PMDA)
	GMP status of the firm	Certificate no 43/2023-dRAP-k dated 03-03-23
	Evidence of approval of manufacturing facility	No F.2-5/2009-Lic dated 03-03-23 mentioning sachet section
	Evaluation Remarks	
	Decision	
	Deferred Deferred for submission of Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
1023	Case Category	New Molecule/Formulation (Shahrukh Ali)
	Name, address of Applicant.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)**
	Application Form Dy. No / Tracking ID & date of submission	(PNW-H9Q-G3MV, 2025-05-13)
	Detail of Fee Submitted	75000.0, 2025-02-03,
	The proposed proprietary name / brand name	**Olapin 1% dry syrup**
	Label Claim	1gram of Powder contains 10mg of Olopatadine Hydrochloride
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100's-As per SRO,20's-As per SRO,30's-As per SRO,50'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)	Selective Histamine H1-Receptor Antagonist (ATC code: S01GX09)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	C-1/ B, 57, LIC SECTOR, G.I.D.C.VAPI - 396 195 DlST.- Valsad
	Detail of stability batches of drug product	3 batches Batch Size 1000 sachet
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: K-1997646088216 Date of issue: 14-Jun-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Olopatadine Hydrochloride Dry syrup 1 % "Nippon zoki pharmaceutical"
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Pharmaceuticals and Medical Devices Agency (PMDA)
	GMP status of the firm	Certificate no 43/2023-dRAP-k dated 03-03-23
	Evidence of approval of manufacturing facility	No F.2-5/2009-Lic dated 03-03-23 mentioning sachet section

	Evaluation Remarks	
	Decision	
	Deferred Deferred for submission of Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
1024	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**Pacific Pharmaceuticals Ltd.** Plot No.384, Sundar Industrial Estate, Raiwind Road, Lahore **(000902)**
	Application Form Dy. No / Tracking ID & date of submission	(RB4-9SN-WP57, 2025-05-12)
	Detail of Fee Submitted	37000.0, 2025-02-14,
	The proposed proprietary name / brand name	**Nuroven Injection 500µg**
	Label Claim	Each ampoule contains: Mecobalamin.....500µg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1ml x 10 Injections-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 C
	For generic drugs (me-too Status)	Mecomed Injection 500µg/ml by Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Micro Orgo Chem-57, C1-B, LIC Sector G.I.D.C, Vapi, Gujarat- 396 195 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	PMDA Japan Approved-Methycobal Injection 500 µg by Eisai Co., Ltd. Tokyo
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has submitted stability data with identical chromatograms and retention time throughout stability data of product.	
	Decision	
	Rejected Firm has submitted stability data with identical chromatograms and retention time throughout stability data of product.	

Item No. III Division of Quality Assurance & Laboratory Testing

S. No.	CASE TITLE
1.	**Substandard Famila 28f Tablet, Reg. No. 023941 Manufactured By M/S Zafa Pharmaceuticals Laboratories (Pvt) Ltd, Karachi**
2.	**Manufacture And Sale of Substandard Ciprozat 500mg Tablet Reg No. 031221 Batch No. 2421 Manufactured By M/S Hizat Pharmaceutical Industry Peshawar**
3.	**Manufacture And Sale of Sub-Standard Azofin Suspension, Reg. No. 020860 Kemycone Suspension Reg. No. 025623 Manufactured By M/S. Alkemy Pharmaceutical Laboratories (Pvt) Ltd, P-9, S.I.T.E., Hyderabad**

CASE NO.1: <u>SUBSTANDARD FAMILA 28F TABLET, REG. NO. 023941 MANUFACTURED BY M/S ZAFA PHARMACEUTICALS LABORATORIES (PVT) LTD, KARACHI.</u>

The Federal Inspector of Drugs, DRAP, Karachi (Mr. Hakim Masood) in compliance to the direction contained on M/s Zafa 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. Samples 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 Zafa 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. Zafa 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 28th July, 2025,
2.	Tab. Famila 28F **Reg. No** 023941	M/s. Zafa 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*** Limit: meets the requirements **Assay (Levonorgestrel):134.8%** ***Does not comply*** Limit: 90.0% to 110.0%	PWD-5-25-000129 dated 17th July, 2025
3.	Tab. Famila 28F	M/s. Zafa Laboratories, A-46, SITE	K-203	05-2025	05-2028	Sample has been declared as "***Substandard"*** on the basis of	PWD-6-25-000148 dated 17th

	Reg. No 023941	North Karachi				**Weight variation (Ferrous Iron)** ***Does not comply*** Limit: meets the requirements	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 17th 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 28th 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 **Assay (Levonorgestrel):26.3%** ***Does not comply*** Limit: 90.0% to 110.0%	PWD-5-25-000137 dated 28th July, 2025
7.	Tab. Famila 28F	M/s. Zafa Laboratories, A-46, SITE	K-191	05-2025	05-2028	Sample has been declared as "***Substandard"*** on the basis of	PWD-5-25-000138 dated 28th

	Reg. No 023941	North Karachi				**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%	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 28th 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 28th 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 "***Substandard"*** on the basis of **Content Uniformity (Ethinyl Estradiol)** ***Does not comply*** Limit: meets the requirements	PWD-6-25-000149 dated 28th July, 2025

						Weight variation (Ferrous Iron) ***Does not comply*** Limit: meets the requirements	
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 "***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-6-25-000150 dated 28th 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 "***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):134.0%** ***Does not comply*** Limit: 90.0% to 110.0%	Test report No. PWD-5-25-000133 dated 31st 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 "***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):144.0%**	PWD-5-25-000136 dated 29th July, 2025

						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 18th 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 **Assay (Levonorgestrel):35.6%** ***Does not comply*** Limit: 90.0% to 110.0% **Assay (Ethinyl estradiol):25.5.0%** ***Does not comply***	PWD-5-25-000139 dated 23rd July, 2025

						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 23rd 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 1st August, 2025
18.	Tab. Famila 28F **Reg. No** 023941	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 **Content Uniformity (Levonorgestrel)** **Does not comply** Limit: meets the requirements **Weight variation (Ferrous**	PWD-5-25-000090 dated 12th August, 2025,

						Iron) ***Does not comply*** Limit: meets the requirement	
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 13th 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)** ***Does not comply*** Limit: meets the requirements **Assay**	PWD-5-25-000142 dated 12th August, 2025

						(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 13th August, 2025

4. Federal Inspector of Drugs Karachi 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

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 28th July, 2025
	Tab. Famila 28F	K-177	PWD-5-25-000129 dated 17th July, 2025
	Tab. Famila 28F	K-203	PWD-6-25-000148 dated 17th July, 2025,
	Tab. Famila 28F	K-207	PWD-6-25-000152 dated 17th July, 2025
	Tab. Famila 28F	K-184	PWD-5-25-000132 dated 28th July, 2025,
	Tab. Famila 28F	K-190	PWD-5-25-000137 dated 28th July, 2025
	Tab. Famila 28F	K-191	PWD-5-25-000138 dated 28th July, 2025
	Tab. Famila 28F	K-182	PWD-6-25-000146 dated 28th July, 2025
	Tab. Famila 28F	K-199	PWD-6-25-000147 dated 28th July, 2025
	Tab. Famila 28F	K-204	PWD-6-25-000149 dated 28th July, 2025
	Tab. Famila 28F	K-205	PWD-6-25-000150 dated 28th July, 2025,

report from FID, Lahore for following batches

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 31st July, 2025
	Tab. Famila 28F	K-187	PWD-5-25-000134 dated 18th July, 2025,
	Tab. Famila 28F	K-189	PWD-5-25-000136 dated 29th July, 2025
	Tab. Famila 28F	K-192	PWD-5-25-000139 dated 23rd July, 2025
	Tab. Famila 28F	K-194	PWD-5-25-000140 dated 23rd July, 2025,
	Tab. Famila 28F	K-195	PWD-5-25-000141 dated 1st 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 13th August, 2025
	Tab. Famila 28F	K-196	PWD-5-25-000142 dated 12th August, 2025
	Tab. Famila 28F	K-197	PWD-5-25-000143 dated 13th August, 2025
	Tab. Famila 28F	K-159	PWD-5-25-000090 dated 12th 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:
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 Fumerate, which is titration method.
b. The testing method is verified in accordance with ICH guideline Q2(R1)
c. Weight variation of Ferrous Fumerate is performed during in-process control as per BP specifications, applying a ±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 Levonrgestrel 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 Levonrgestrel 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 shall decide the request for appellate testing under Section 22(5) of the Drugs Act, 1976".

14. Dr. Awais Ahmed Area FID, DRAP, Karachi submitted PSI report. Inspection was conducted on 4th April 2026 against DRAP letter for Product Specific Inspection of substandard Famila 28F Tablet

15. Following panel conducted PSI for product Famila 28F Tablet, *Registration No. 023941* on 4th April, 2026 in compliance to letter No. 03-02/2026-QALT(353-RB) dated 12th February, 2026.

i. Mr. Abdul Rasool Sheikh, Additional Director, DRAP, Karachi
ii. Mr. Abdul Wheed, Deputy Director, I&E, DRAP, Karachi
iii. Dr. Awaise Ahmed, Area FID, DRSAP, Karachi.

16. During the PSI, a comprehensive and detailed evaluation of the manufacturing process and testing methods should have been conducted to identify the root cause(s) of the substandard batches of Famila 28F Tablets. However, no such detailed assessment has been carried out. Specifically, the evaluation of manufacturing procedures and testing methods is inadequate; testing method protocols and validation of analytical procedures in accordance with USP requirements have not been addressed. Furthermore, relevant HPLC records, including chromatograms, have also not been provided. The manufacturing details are incomplete, as the batch size and its validation has not been provided and the manufacturing process has not been thoroughly evaluated. Overall, the Product-Specific Inspection Report lacks critical details and is deficient in several key aspects.

17. It is further submitted that the Federal Inspector of Drugs, Karachi collected samples on 22-05-2025 and 04-06-2025. The test reports were subsequently received during the months of July and August. Upon receipt of reports from CDL declaring the samples of Famila 28F Tablets as of "substandard quality", the Federal Inspector of Drugs, Karachi forwarded the Board's portion to Islamabad, which was received on 28-07-2025.

18. It has been observed that the board portion of the samples were sent by the FID in violation of Section 19(3) of the Drugs Act, 1976, and were not dispatched in accordance with the provisions of Section 19(2) of the said Act. Consequently, the integrity of the samples is considered doubtful.

19. Accordingly, the matter was processed and an inquiry was initiated against the FID, Karachi.

20. **Proceedings and Decision of 357th meeting of Registration Board**

Representatives from Division of QA&LT presented the case before the Board for consideration. The Board examined the matter in detail. After thorough deliberation of the available record the Board observed that the sample had been received in contravention of the provisions of Section 19(3) as well as Section 19(2) of the Drugs Act, 1976.

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

i. Fresh sampling of all batches of Famila 28F Tablets lying at the Directorate of Central Warehouse & Supplies, F-508, SITE, Karachi by the area Federal Inspector of Drugs (FID) in the presence of the Director, QA&LT to ensure transparency and regulatory compliance.

ii. Subsequently, the duly sealed and documented samples shall be dispatched to the Central Drugs Laboratory (CDL) for test and analysis. The results thereof shall be submitted to the board for further necessary regulatory action.

21. Decision of Registration Board was communicated to FID vide F.03-20/2026-QALT (357-RB) dated 4th June, 2026.

22. Firm submitted their response and did not agree with the decision of the Registration Board and requested to send the samples for re-testing under Section 22 (5) of the Drugs Act 1976.

23. **Proceedings and Decision of 361st meeting of Registration Board**

i. The QA&LT Division presented the case before the Registration Board. The Registration Board remanded the case with the observation that the Board has already taken a decision in the matter in its 357th meeting. If the firm is aggrieved with the said decision of Registration Boar, the firm may file an appeal before the Appellate Board under Section 9 of the Drugs Act, 1976.

ii. Registration Board endorsed and authorized the practices of QA&LT Division since long for handling of Board's portion of sample sent by FID and I&E officers under section 19(ii) of the Drugs Act 1976 and as per SOP (QALT/SOPA4S/024).

Case No.2: MANUFACTURE AND SALE OF SUBSTANDARD CIPROZAT 500MG TABLET REG NO. 031221 BATCH NO. 2421 MANUFACTURED BY M/S HIZAT PHARMACEUTICAL INDUSTRY PESHAWAR

The Federal Inspector of Drugs, DRAP, Peshawar (Mr. Shahid Nawaz) visited the premises of M/s Hizat Pharmaceutical Industry Peshawar on 18th November 2025 and took samples of the Ciprozat 500mg Tablet on Form-3 and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4.

2. Federal Government Analyst, CDL Karachi vide test report No. IP-12-25-000155 dated 17th February 2025, declared the batch 2421 of product Ciprozat 500mg Tablet manufactured by M/s Hizat Pharmaceutical Industry 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
Ciprozat 500mg Tablet (Ciprofloxacin : 500mg/tablet)	M/s Hizat Pharmaceutical Industry Peshawar	031221	2421	04-2025	04-2028	***"Sub-Standard"*** on the basis of Dissolution Stage 1: Does not comply (Stage 2) : 74% ***Does not Comply*** Limit: Average of 12 NLT Q=80. Each unit should not be less than Q-15=6

3. Federal Inspector of Drugs, DRAP, Peshawar, submitted the company's request of Appellate testing vide letter No. HZ/HCl/03/26 dated 9th March, 2026 (after receiving letter along with CDL report from FID, Peshawar (which was sent on 3rd March, 2026)

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.03-10/2026-DD(QALT) dated 2nd April, 2026, requested the Federal Government Analyst CDL Karachi and M/s Hizat Pharmaceutical Industry Peshawar 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 the USP 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 Hizat Pharmaceutical Industry Peshawar:
M/s Hizat Pharmaceutical Industry Peshawar, in their reply that an OOS investigation was conducted on the retained samples of the subject batch in our Quality Control laboratory. The dissolution testing was carried out on 11-04-2026 under the following conditions Apparatus II (Paddle), Medium: 0.01N HCI 900ml, Temperature: 37°C RPM 50, Wavelength 277nm, Time: 30 minutes. The results obtained are as follows
Sample 1: 0.673 - 96.02%
Sample 2: 0.683 - 97.43%
Sample 3: 0.674 - 96.14%
Sample 4: 0.701-100.01%
Sample 5: 0.683 - 97.48%
Sample 6: 0.688 - 98.23%
Average: 97.55%
Limit: NLT 80% (Q)

Remarks: Complies Specifications

The OOS investigation results were found satisfactory. All six units complied with the dissolution specification, with an average dissolution of 97.55% against the limit of NLT 80% (Q). No out of Specification result was observed during retained sample testing.

Scientific Justification for Appellate Testing:
It is most respectfully submitted that the test report issued by CDL Karachi cites USP-NF 2025 as the reference standard. The USP General Chapter <711> on Dissolution prescribes a mandatory three-stage sequential testing protocol (S1, S2, and S3). The CDL has conducted testing only up to Stage 2 (S2) and has not proceeded to Stage 3 (S3), despite the S2 result not meeting the acceptance criteria. Under USP <711>, when S2 criteria are not met, testing must mandatorily proceed to Stage 3 (S3) before any final conclusion can be drawn. Declaring a product Substandard without completing Stage 3 (S3) of the prescribed protocol as required by the very reference standard cited in the CDL report-constitutes an incomplete and premature analytical conclusion.

7. Proceedings and Decision of 360th meeting of Registration Board

Division of QA & LT presented the case before the Registration Board. The Board, after considering facts of the case, thoroughly deliberation and considering the OOS investigation, decided as follows:

i. ***It was observed that stance of the firm that CDL has not proceeded for Stage 3 is not scientifically justifiable as during Stage 2 testing, one of their tablet is having test results of 53%, which renders product not to qualify for stage 3 testing (i.e Dissolution test of any tablet should not be lest than Q-15% while dissolution test of one tablet was 53%. Hence Registration Board did not accede request of the firm for appellate testing of Ciprozat 500mg Tablet (Ciprofloxacin Hcl) manufactured by M/s Hizat Pharmaceutical Industry Peshawar from Appellate Laboratory under section 22 (5) of the Drugs Act, 1976.***

ii. ***To issue show cause notice to M/s Hizat Pharmaceutical Industry 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***.

2. In the light of decision of Registration Board a Show Cause notice vide No F.03-26/2026-QALT (360-RB) dated 5th August 2026 under Section 42 of the Drugs Act 1976 was issued to the firm.

3. In response, M/s Hizat Pharmaceutical submitted their reply and requested for appellate testing of the subject batch and an opportunity of personal hearing, through its authorized representative, before the Registration Board prior to any final decision in the matter.

4. Accordingly, the firm had been issued notice of personal hearing to appear before the Board, vide office letter No F. No.03-33/2026-QALT (361-RB) dated 13th August 2026 under Section 42 of the Drug Act 1976.

5. **Proceedings and Decision of 361st meeting of Registration Board**

Division of QA & LT presented the case before the Registration Board. Mr. Asif Raza Production Manager of M/s Hizat Pharmaceutical Industry Peshawar appeared before Board and reiterated that he had already submitted the detailed written reply on the matter,

The Board, after considering the facts of the case and after thorough deliberation, decided as follows:

i. ***Product-specific inspection, including verification of the Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA), conducted by a panel of inspectors/experts to be nominated by the Director (QA/LT).***

ii. ***Suspension of the Registration of Ciprozat 500mg Tablet Registration No.*** **031221** ***manufactured*** **by** ***M/s Hizat Pharmaceutical Industry Peshawar under section 42 of the Drugs Act, 1976 and rules framed thereunder, for a period of six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by a panel with satisfactory report; whichever is earlier.***

iii. ***Destruction of the recalled stock under the supervision of Area FID.***

Case No. 3. MANUFACTURE AND SALE OF SUB-STANDARD AZOFIN SUSPENSION, REG. NO. 020860 KEMYCONE SUSPENSION REG. NO. 025623 MANUFACTURED BY M/S. ALKEMY PHARMACEUTICAL LABORATORIES (PVT) LTD, P-9, S.I.T.E., HYDERABAD

Background of the case:

Dr. Abdur Rashid, Additional Director (QA&LT) along-with Syed Hakim Masood, Area FID, Karachi conducted inspection of the firm M/s Alkemy Pharmaceutical, Hyderabad on 16.11.2016 in connection to Quality Control letter dated 27.05.2016, wherein the firm was found in manufacturing and sale of sub-standard drug Azofin suspension, Kemycone suspension and to verify GMP compliance / production activities of the firm.

2. The panel noticed number of critical observations, which need urgent attention and rectification. The observations includes:-

i. No traceability of Raw Materials was available. No proper records were available. No thermometer and hygrometer were found for recording of temperature and humidity in the warehouse.
ii. Dispensing Areas needs renovation and additional calibrated weighing balance required.
iii. Old silverson mixers are rusted/old and required to be placed with new ones.
iv. Storage tanks required to be replaced with new ones.
v. Floor, walls and ceiling are cracked/old and needs overall, renovation required.
vi. The rodents and insects can enter from drainage in the production of syrup section and so requires better drainage system.
vii. Vessels need to be replaced.
viii. Liquid filling machine is old and rusty and must be replaced with semi-automatic filling machine with conveyor belt.
ix. Water System needs to be upgraded with new one.
x. Batch Manufacturing instructions were missing from batch manufacturing records.
xi. Iron racks are required to be placed in the warehouse. Iron and plastic pellets maybe further added in the warehouse and wooden pellets should be removed from the area.
xii. There are no racks in the finished goods store and medicines are placed on the floor. Few wooden pellets and plastic pellets are also seen in one room. There is a need that iron racks and plastic pellets maybe provided along with hygrometers to monitor the humidity of the finished goods store. Floor walls and ceiling needs renovation paint and up gradation.
xiii. Dust can enter from the open exhaust, therefore an exhaust is required.
xiv. There is overall need to upgrade the facility in the chemical and microbiological sections of the QC laboratory. No HPLC is available, so one HPLC may be provided.
xv. There is lacking of proper log book of the equipments, calibration, and validation of the analytical methods.
xvi. Viscometer is no more available to measure the viscosity of suspension.
xvii. In microbiological section, autoclave, colony counter and refrigerator are no more available. It is recommended to provide the same.
xviii. The qualified person in chemical and microbiological section needs training and has lack of latest knowledge. It is recommended that the technical personnel may be sent to Karachi for proper training.
xix. Qualified persons documents were submitted in 2013, but have not been approved by the concerned division.
xx. Packaging materials and labels are not properly stored and documented.

The panel concluded that:- The observations were discussed with the management and the management of the firm voluntarily stopped production in the liquid syrup section for maintenance and renovation. The panel recommended to issue a show cause notice for Liquid Section and personal hearing be given to the representative of the firm for cancellation and suspension of DML.

4. **Action taken by DRAP:** Accordingly show cause notice / suspension of production activities in liquid syrup section was issued to the firm on 09.01.2017.

5. **Reply by the firm:** The firm vide letter dated 17.01.2017 submitted reply, requested that the facility has been maintained and requested for the constitution of the panel to visit the firm and to provide opportunity for personal hearing.

6. Proceedings of the 252nd Meeting of CLB

The Board was informed by the Deputy Director (QA) that the samples of Azofin Suspension and Kemycone Suspension were declared as of substandard quality by the Central Drugs Laboratory, Karachi. Accordingly, the case was placed in 258th meeting of Registration Board held on 25th and 26th April, 2016. The Registration Board constituted panel of experts comprising of Dr. Abdur Rashid, Additional Director (QA&LT) and Syed Hakim Masood, Area FID to conduct PSI. The panel conducted inspection of the firm on 16.11.2016 and observed gross violations in Liquid Syrup Section. Accordingly, show cause notice / suspension of production activities in liquid syrup section was issued to the firm on 09.01.2017. The firm was served letter for personal hearing on 08.03.2017. Mr. Faraz Ahad Shaikh, Managing Director and Mr. Asif Najeeb Laghari, QC In-charge appeared before the Board. Managing Director inform the Board that they voluntarily stop the production in liquid section. He added that the

observations noted by the panel have been rectified and they are ready for inspection. The Board inquired regarding availability of FTIR, Viscometer and Polarimeter in the Quality Control Lab. The QC In-charge replied in negative. The Board took serious notice of non-availability of most important equipment used for testing of liquid products, in QC Lab.

Decision of the 252nd Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendations of the panel of experts in its report dated 16.11.2016, casual attitude of the firm towards GMP compliance in liquid syrup section, the Board decided to:-

i. *Suspend the Drug Manufacturing License of liquid syrup section of the firm M/s Alkemy Pharmaceutical Laboratories (Pvt) Ltd, Karachi, for a period of 03 months under section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (LR&A) Rules, 1976, from the date of issuance of decision of the 252nd meeting of CLB.*

ii. Conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976, after submission of compliance report by the firm, by the following members:-

- *Syed Muid Ahmad, Member CLB*
- *Dr. Abdur Rashid, Additional Director (QA&LT), Islamabad.*
- *Syed Hakim Masood, Area FID, Hyderabad / Karachi*

iii. The Board also decided to direct the panel to submit brief report in tabulated form identifying the previous observations and the current status with clear and candid recommendations.

iv. The report shall be presented in the meeting of Central Licensing Board for perusal and approval.

7. In compliance of the decision of CLB, QA&LT Division issued latter No.8-1/2017-QA) (M-252-CLB) dated 24" April 2017 for verification of the observations noted by the panel in PSI conducted on 16-11-2016. Accordingly, the panel conducted GMP inspection of the firm, on 26" July 2017. The Panel recommended for resumption of production in syrup section, which suggest PSI was already conducted and observations were verified in inspection of 26th July 2017 but PSI report was not available in record.

8. Therefore, the Director QA&LT Division constituted the following panel to conduct PSI of the firm M/s Alkemy Pharmaceutical Laboratories, Hyderabad vide letter F.No.13-45/2025-DD(QALT)-VI dated 08-01-2026:

i. Additional Director, DRAP, Karachi
ii. Area FID (Reporting & Coordinating Officer).
iii. DD (I&E)

9. The Panel visited the firm on 10-04-2026 and submitted the inspection report which is being reproduced below:

"BACKGROUND & HISTORY

Alkemy Pharmaceuticals Laboratories Private Limited, site area Hyderabad, was visited on 10th April 2026 for Product specific inspection of Kemycone suspension containing (Aluminum Hydroxide, Magnesium Hydroxide and Semithicone) batch number 293." Kemycone suspension was declared substandard due to potency by the Central Drug Laboratory, DRAP Karachi vide No. Nil dated 11" Nov 2015. Firm challenged the CDL report and requested for Appellate testing. The appellate laboratory also declared the sample as substandard vide report 01-M/2016 dated 29" February 2016. Case was placed in CLB meeting held on 26h April 2016 and decided to suspend the registration for 06 months and conduct PSI by the panel and firm would recall the batch and area FID would supervise the destruction. During record evaluation, firm shown GMP inspection, conducted by the panel on 26" July 2017, in compliance to DRAP Islamabad &-1/2017-QA) (M-252-CLB) dated 24" April 2017 for verification of the observations noted by the panel in PSI conducted on 16-11-2016. The Panel recommended for resumption of production in syrup section (Report attached), which suggest PSI was already conducted and observations were verified in inspection of 26" July 2017 but PSI report was not available in record.

MEETING WITH THE MANAGEMENT AND TECHNICAL TEAM:
During discussion with the management of the company, Mr. Faraz Sheikh briefed the panel (copy attached) that they retested the retention sample and it was standard in retest results, as product was unstable in high temperature, they have not been paying the renewal fees of the registration since then, and they are not willing to continue the product (Letter attached).

PROCEEDINGS OF THE INSPECTION:
During visit, it was observed that some of the areas were under renovation for which firm had approved layout plan. Firm was granted new sections in new approved layout, Panel observed that almost work had been completed. During batch related record evaluation, it was observed that, sample was retested by the firm, but raw data related to retest was not available, however, original testing report was available at the site. BMR was available, and found no deviation from the approved method. Afterwards, QC facility was inspected where panel found firm had sufficient equipment for testing of the samples, including but not limited to HPLC, UV meter, pH meter, analytical balances, dissolution operators, disintegration operators, etc. were available. FTIR was out of order and out for repair. Work order was available and verified. Other equipments included oven, moisture analyzer, friability operators, stability chamber, hardness tester etc. were available. Furthermore, firm management informed that, in compliance to the CLB decision, they had initiated the recall but no return was reported, As batch was manufactured in July 2015 and recall was started on 27" May 2016, after lapse of almost 10 months, therefore no return was reported. because quantity was less i.e. total 4156 bottles.

CONCLUSION & RECOMMENDATION:
Keeping in view the above mentioned facts letter by the firm (copy attached) to withdraw the registration of the product it is concluded that, TORs of the PSI could not be verified on the basis of product discontinuation and registration of the product Kemycon suspension may kindly be cancelled."

10. Based on the conclusion of the panel in the PSI report, a show cause notice was issued to the firm, and they were also directed to appear before the Registration Board in its 360th Meeting to be held on 30-06-2026 vide letter No.F.03-26/2026-QALT-(RB-360) dated 23-06-2026.

11. Due to postponement of 360th meeting of the Registration Board, the new date i.e., 07-07-2026 was communicated to the firm vide letter No.F.03-26/2026-QALT-(RB-360) dated 29-06-2026

20. The firm had been called upon for Personal Hearing, however, no one from the firm appeared before the Board.

21. <u>Proceedings and Decision of 360th meeting of Registration Board</u>
Division of QA & LT presented the case and apprised the Registration Board that no request of the firm for cancellation of Registration of Kemycone suspension, as noted by the panel in inspection report, has been received in PE&R Division or QA&LT Division. No one on behalf of firm appeared before the Board.
The Board, after considering the facts of the case, and thorough deliberations, decided to:

i. *Verify the Registration status of both Azofin Suspension (Reg# 020860) and Kemycone Suspension (Reg# 025623). manufactured by M/s. Alkemy Pharmaceutical (Pvt) Ltd, Hyderabad.*
ii. *Suspend the Registration of Azofin Suspension (Reg# 020860) and Kemycone Suspension (Reg# 025623). manufactured by M/s. Alkemy Pharmaceutical (Pvt) Ltd, Hyderabad till the next meeting of the Registration Board.*
iii. *Direct the firm to submit their request for cancellation of Registration of both products in writing to the PE&R Division under intimation to the QA&LT Division, as per report of panel.*
iv. *Call the firm for Personal Hearing in the next meeting of the Registration Board as a final chance to be heard in person.*

6. The decision of Registration Board was communicated vide office letter No .03-26/2026-QALT (360-RB) dated 5th August 2026 to the firm

7. Accordingly, the firm has been issued notice of personal hearing to appear before the Board, vide office letter No F. No.03-33/2026-QALT (361-RB) dated 13th August 2026 under Section 42 of the Drug Act 1976.

8. **Proceedings and Decision of 361st meeting of Registration Board**

Division of QA & LT presented the case before the Registration Board. Mr. Faraz Ahmad Shaikh Managing Director of M/s Alkemy Pharmaceutical Laboratories appeared before Board, and submitted that they had applied for the renewal of Azofin Suspension Reg. No. 020860 and want to continue this product, however with regard to Kemycone Suspension Reg.No 025623 they want to voluntarily withdraw registration and have not applied for renewal of Registration in last 10 year. The Board directed the representative of the firm to submit evidence of renewal of Registration application for their product Azofin Suspension Reg. No. 020860. Till date renewal Status of Azofin Suspension has not been submitted by Firm; according to renewal section of the PE&R Division, the last application for renewal for Azofin suspension was applied in January, 2018.

The Board, after considering the facts of the case and after thorough deliberation, decided as follows:

i. ***The registration of Kemycone Suspension, Reg. No. 025623, stands invalid and cancelled as no renewal application was submitted by the firm.***
ii. ***The case regarding confirmation of registration status of Azofin Suspension Reg. No. 020860 will be referred to the PE&R Division.***
iii. ***In case registration stands valid, for Azofin Suspension (Reg# 020860), it will remain suspended till submission of product development and stability data and its subsequent approval by the Registration Board.***

Drug Regulatory Authority of Pakistan

(Pharmaceutical Evaluation & Registration Division)

******

Item No. IV Division of Biological Evaluation & Research

Sr. No	Title	Description
1	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Citi Pharma Limited** 3 KM, Phool Nagar, Head Balloki Road, Kasur-Pakistan **(05-351-0073-130312D)**
	Application Form Dy. No / Tracking ID & date of submission	(6N3-Y3Z-QS1R, 2026-07-07)
	Detail of Fee Submitted	313500, 2026-02-12,
	The proposed proprietary name / brand name	**Citulin-R 100 IU/ml Suspension for Injection Isophane**
	Label Claim	Each ml contains: Mixed Isophane Insulin Human Suspension.....100 IU Human Insulin Ph. Eur. ....100 IU [70% Human Insulin Isophane Suspension, 30% Human Insulin Injection (rDNA Origin)] (As per Ph. Eur specs)
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1's (3mL Cartridge)-As per SRO
	Shelf Life (Unit)	3 Year(s)Store between 2°C to 8°C in a refrigerator. Do not freeze.
	For generic drugs (me-too Status)	Insuget 70/30 BY M/s Getz Pharma
	Pharmacotherapeutic Group of (API)	Insulin
	Name, address of Manufacturing site:	Fosun Wanbang (Jiangsu) Pharmaceutical Group Co., -7 South Road of Pantao Hill, Jinshanqiao Economic Zone, Xuzhou, Jiangsu Province: Therapeutic biologicss-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	-
	Name, address of Marketing Authorization Holder:	Fosun Wanbang (Jiangsu) Pharmaceutical Group Co.,, 7 South Road of Pantao Hill, Jinshanqiao Economic Zone, Xuzhou, Jiangsu Province: Therapeutic biologicss, 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	Humulin®70/30 [70% Human Insulin Isophane suspension 30% Human Insulin (rDNA origin)], 100 units/mL (U-100) M/s Lilly USA, LLC, Indianapolis, IN 46285, USA, USFDA Approved.
	Evaluation Remarks	
	An application for insulin glargine (cartridge) from the same manufacturer, bearing Tracking ID NBU-WMN-RMTD, was rejected during the 359th meeting of the Registration Board (RB) due to	

	the non-availability of a dedicated biotechnology (rDNA) manufacturing facility at the manufacturer's site. The current application is of Mixed Isophane Insulin Human Suspension (cartridge) from the same manufacturer.	
	Decision	
	Rejected Registration Board rejected the application due to non-availability of dedicated Biotech (rDNA)facility.	
2	Case Category	Routine (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	(8MH-NBA-MDW4, 2026-04-06)
	Detail of Fee Submitted	75000, 2026-03-26,
	The proposed proprietary name / brand name	**Semma 4mg Tablet**
	Label Claim	Each Tablet Contains: SEMAGLUTIDE.....4mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui 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	EMA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The application fulfills the codal formalities. Submitted for consideration by the Board.	
	Decision	
	Approved Approved as per innovator's specifications with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into	

	the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
3	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**BF Biosciences Limited** 5-KM Sundar Raiwind Road, Raiwind, Lahore **(000655)**
	Application Form Dy. No / Tracking ID & date of submission	(HN3-P6M-ZX3Q, 2025-07-09)
	Detail of Fee Submitted	37000.0, 2024-11-21,
	The proposed proprietary name / brand name	**Peg-Filgen PFS 6mg/0.6ml**
	Label Claim	Each PFS (0.6ml) Contains: Peg-Filgrastim.....6mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2°C to 8°C.
	For generic drugs (me-too Status)	Neulastim 6mg of M/s Roche Pakistan Ltd.
	Pharmacotherapeutic Group of (API)	Immunostimulants (Colony Stimulating Factors) ATC Code : L03AA13
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name: Zydus Lifesciences Ltd., Address: Zydus Biologics (Unit-1) Plot No. 23, 25/P, 37, 40/P, 42 TO 47, Sarkhej – Bavla, N.H. 8A, Changodar Road, Opp. Ramdev Masala, Ahmedabad – 382213, Gujarat, India
	Detail of stability batches of drug product	Accelerated stability testing was performed on three batches—047D0 (Batch size 237 PFS) 1, 047D02 (236 PFS), and 047D03 (236 PFS)—at a temperature of 25°C (±2°C) and relative humidity of 60% RH (±5%) till 6 months. In parallel, real-time stability studies were carried out on the same three batches at a temperature of 5°C (±3°C) till 6 months.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate Computerized No. 6461022241693 dated 04-09-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches DS-403-001, DS-403-002, and DS-403-003 at accelerated conditions with time intervals 0, 1st, 2nd ,3rd, 6th. The real time stability data is

	conducted at 25 ± 5 °C, at the intervals of 0, 3rd, 6th , 9th , 12th , 18th , 24th , 36th months.
The status in reference regulatory authorities	NEULASTA Injection of Amgen Inc. One Amgen Center Drive Thousand Oaks, California approved by USFDA
GMP status of the firm	GMP certificate was issued to M/s BF Biosciences on 05-09-2024.
Evidence of approval of manufacturing facility	Pre-filled syringe section granted on 07-05-2024.

Evaluation Remarks

The application was evaluated and some queries were asked from the applicant. The reply of the applicant is tabulated below along with remarks;

Sr.No.	Queries	Response of the firm	Remarks
1	Manufacturer mentioned in the dossier is M/s Zydus Lifesciences India while the manufacturer as per clearance certificate, Form 3 and Form 7 is M/s Candila Healthcare India. Clarification required.	Cadila Healthcare is the former name of Zydus Lifesciences Limited; the company officially changed its name in 2022. Mfg. license is attached as Annexure A for Clarification	Evidence of approval of change of name of manufacturer by their regulatory authority is required.
2	Submit Legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk.	CoPP from the Country of Origin is attached as Annexure B	COPP of final product tha has been manufactured by same concentrate/ready to fill bulk is required.
3	Submit complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity.	Not Applicable as it is a generic product. The comparative studies with the reference product are attached in Annexure F.	The product is of rDNA origin. Complete Bio-similarity required including non-clinical and clinical part also.
4	Submit Module 3.2.S.2.2 to 3.2.S.2.6	Module 3.2.S.2.2 to 3.2.S.2.6 attached as Annexure C	Submitted.
5	Provide agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Quality Agreement between BF Biosciences Ltd. & Zydus Lifesciences is attached as Annexure D	Required agreement not provided.

6	Submit Raw data and chromatograms of stability data of finished product.	Its testing is bioassay based. Raw Data sheets of Bioassay are attached as Annexure E.	Complete raw data of all the tests performed in stability of finished produ is required.
7	Comparative testing of finished product is performed with Neupeg of M/s Intas Pharmaceuticals India which is not innovator product.	At the time of testing, the innovator product NEULASTA® (pegfilgrastim) injection was not available. So, we performed comparative testing with Neupeg (M/s Intas Pharmaceuticals India). Comparative Studies are attached as Annexure F.	Comparative testing of applied product with innovator is required.
8	Undertakings required as per guidelines of bulk concentrate import approved in 278th meeting.	Attached as Annexure G.	Not provided.

Concluding remarks: i. Evidence of approval of change of name of manufacturer by their regulatory authority is required. ii. COPP of final product that has been manufactured by same concentrate/ready to fill bulk is required. iii. Complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity is required. iv. Complete raw data of all the tests performed in stability of finished product is required. v. Comparative testing of applied product with innovator is required. vi. Undertakings required as per guidelines of bulk concentrate import approved in 278th meeting. vii. Agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents. Decision of 359th meeting: Deferred Registration Board deferred the application for submission of following documents; Complete quality comparison of the product manufactured by the local manufacturer using the proposed drug substance with the innovator product including comprehensive comparative characterization encompassing all relevant physicochemical, structural, biological, and purity attributes. Comparative bioassays including receptor-binding studies and functional assays (e.g. cell proliferation assay) with innovator. PK/PD studies of the drug product manufactured by the local manufacturer using the proposed drug substance demonstrating comparability of the product with the innovator and to support the similarity of the finished product. Remarks of BE&R:

S.No.	Queries	Response	Remarks
1	Complete quality comparison of the product manufactured by the local manufacturer using the proposed drug substance with the innovator product including comprehensive comparative characterization encompassing all relevant physicochemical, structural, biological, and purity attributes.	Detailed comparative quality characterization of the Peg-Filgen Injection (BF Biosciences Ltd.) has been conducted against the innovator product, Neulastim Injection. The comparison includes detailed evaluation of all relevant physicochemical, structural, biological, and purity attributes. The detailed comparative quality characterization report is attached as Annexure 1	Firm has performed comparative studies of applied product with the innovator on Finished product specification parameters. Comparative structural characterization is not performed.
2	Comparative bioassays including receptor-binding studies and	Comparative bioassays of Peg-Filgen Injection (BF Biosciences Ltd.) verses	Provided

	functional assays (e.g. cell proliferation assay) with innovator.	innovator product, Neulastim Injection attached as Annexure 1 # point 6	
3	PK/PD studies of the drug product manufactured by the local manufacturer using the proposed drug substance demonstrating comparability of the product with the innovator and to support the similarity of the finished product.	The proposed product is not a new formulation but represents only a change in product presentation from the already registered product i-e Peg-Filgen. The same product is already registered under the brand name PEGFILGEN since 2010 and has been successfully marketed and no significant ADR reported till date. The current application differs only in the presentation (Vial to Prefilled Syringe [PFS]), while there is no change in the drug substance, formulation, manufacturing process, manufacturing site, quality control specifications, or critical quality attributes. Furthermore, comprehensive PK/PD and clinical comparability studies were conducted for PEGSTIM (Peg-Filgrastim) Finished Product using the same Drug Substance Peg-Filgrastim manufactured by Zydus Lifesciences Limited, India, demonstrating biosimilarity with the innovator reference product. These studies confirmed comparable pharmacokinetic, pharmacodynamic, efficacy, safety, and immunogenicity profiles between PEGSTIM and the reference product. As the proposed finished product is manufactured using the same Peg-Filgrastim drug substance the previously generated PK/PD and clinical data adequately support the comparability and similarity of the proposed finished product. The detailed PK/PD and clinical study reports, including the comparative evaluation of PEGSTIM versus the innovator reference product, are	Clinical comparability studies are conducted for Finished Product manufactured by Zydus Lifesciences Limited, India using the same Drug Substance Peg-Filgrastim.

		enclosed as supporting documentation for your kind consideration is attached as Annexure 2	

Decision

Deferred

Registration Board decided to defer the case for submission of complete dossier of the finished product manufactured by the drug substance manufacturer, including complete formulation details and analytical procedures.

The Board also approved the following requirements for drug substance import, local manufacturing of rDNA products:

- Comprehensive comparative characterization of the proposed drug substance against the innovator product shall be submitted.
- A complete dossier of the finished product manufactured by the drug substance manufacturer shall be submitted. The local manufacturer shall follow the same manufacturing process and formulation, use the same excipients, and employ the same analytical procedures as those used by the drug substance manufacturer.
- The drug substance manufacturer shall conduct and submit a comprehensive quality comparison of the finished product manufactured using the proposed drug substance with the corresponding innovator product.
- The local manufacturer shall conduct and submit a comprehensive quality comparison of the finished product manufactured using the proposed drug substance with the corresponding innovator product.
- Clinical trial data and/or PK/PD study data conducted in the country of origin using the same drug substance shall be submitted to demonstrate the comparability of the product with the innovator product.

4		
	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**ALLMED LABORATORIES** A-21/3 KDA Scheme 1 Ext. Stadium Road, Karachi **(0388)**
	Application Form Dy. No / Tracking ID & date of submission	(YZ6-S18-WMQJ, 2025-11-03)
	Detail of Fee Submitted	313500.0, 2025-08-22,
	The proposed proprietary name / brand name	**Heparina Duncan**
	Label Claim	Heparin sodium 5000IU/ml
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	pack sizes of 10mlvial -1,6,50,100 ampoules bottle-Controlled
	Shelf Life (Unit)	2 Year(s)Not more than 40°C, preferably between 15°C and
	For generic drugs (me-too Status)	Genereic Name:Heparin sodium Brand Name: Vaxcel Heparin Sodium Injection 5000IU/ml Price :1300.00 Applicant : GHAZALI BROTHERS
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Name, address of Manufacturing site:	Laboratories Duncan S.A-Tronador 543, Autonomous city of Buenos Aires, Argentine Republic-Argentina
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A

	Name, address of Marketing Authorization Holder:	Allmed Laboratories, A-21/3, KDA Scheme 1, Ext opposite National Stadium Karachi-Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP of manufacturer attached
	Details of Authorization Letter :	LOA dated 20-03-2024 attached with validity November 2028.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	attached
	The status in reference regulatory authorities	N/A
	Evaluation Remarks	
	The application was evaluated, and certain queries were raised with the applicant. However, the following queries have not yet been addressed: The attached GMP certificate pertains to pharmaceutical products and does not provide evidence of approval for the manufacturer's biological production facility. Furthermore, the list of products included in the Site Master File consists exclusively of pharmaceutical products. Finished product specifications are not in line with the BP monograph and does not include following tests; Identification by NMR Identification by anti-factor Xa activity Test for Related substances Assay by anti-factor IIa activity. Stability data of 3 commercial batches of drug product at real time and accelerated conditions is required.	
	Decision	
	Deferred Registration Board deferred the case for the submission of following documents/clarifications; 1. The attached GMP certificate pertains to pharmaceutical products and does not provide evidence of approval for the manufacturer's biological production facility. Furthermore, the list of products included in the Site Master File consists exclusively of pharmaceutical products. 2. Finished product specifications are not in line with the BP monograph and does not include following tests; • Identification by NMR • Identification by anti-factor Xa activity • Test for Related substances • Assay by anti-factor IIa activity. 3. Stability data of 3 commercial batches of drug product at real time and accelerated conditions is required.	
5	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**ALLMED LABORATORIES** A-21/3 KDA Scheme 1 Ext. Stadium Road, Karachi **(0388)**
	Application Form Dy. No / Tracking ID & date of submission	(PTH-YJ8-2WVB, 2025-11-21)
	Detail of Fee Submitted	313500.0, 2025-08-15,
	The proposed proprietary name / brand name	**Heparina Duncan**
	Label Claim	Heparin sodium ..... 5000 UI/ml
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	2 Year(s)Not more than 40°C, preferably between 15°C and
	For generic drugs (me-too Status)	Genereic Name:Heparin sodium Brand Name: Vaxcel Heparin Sodium Injection 5000IU/ml

		Price :1300.00 Applicant : GHAZALI BROTHERS
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Name, address of Manufacturing site:	Laboratories Duncan S.A-Tronador 543, Autonomous city of Buenos Aires, Argentine Republic-Argentina
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	Laboratories Duncan S.A, Tronador 543, Autonomous city of Buenos Aires, Argentine Republic, Argentina
	Details of Certificates (CoPP/FSC/cGMP):	GMP of manufacturer attached
	Details of Authorization Letter :	LOA dated 20-03-2024 attached with validity November 2028.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	attached
	The status in reference regulatory authorities	N/A
	Evaluation Remarks	
	The application was evaluated, and certain queries were raised with the applicant. However, the following queries have not yet been addressed: The attached GMP certificate pertains to pharmaceutical products and does not provide evidence of approval for the manufacturer's biological production facility. Furthermore, the list of products included in the Site Master File consists exclusively of pharmaceutical products. Finished product specifications are not in line with the BP monograph and does not include following tests; Identification by NMR Identification by anti-factor Xa activity Test for Related substances Assay by anti-factor IIa activity. Stability data of 3 commercial batches of drug product at real time and accelerated conditions is required.	
	Decision	
	Deferred Registration Board deferred the case for the submission of following documents/clarifications; 1. The attached GMP certificate pertains to pharmaceutical products and does not provide evidence of approval for the manufacturer's biological production facility. Furthermore, the list of products included in the Site Master File consists exclusively of pharmaceutical products. 2. Finished product specifications are not in line with the BP monograph and does not include following tests; • Identification by NMR • Identification by anti-factor Xa activity • Test for Related substances • Assay by anti-factor IIa activity. 3. Stability data of 3 commercial batches of drug product at real time and accelerated conditions is required.	
6	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**GENOME PHARMA** RCCI Industrial Estate, Plot No. C-19, Access Road, Rawat,Islamabad. **(DHO-ISB-2257)**
	Application Form Dy. No / Tracking ID & date of submission	(DTJ-NB8-98XM, 2026-02-23)
	Detail of Fee Submitted	313500, 2026-02-06,

The proposed proprietary name / brand name	**Safacto AF 500 IU Lyophilized Powder for Infusion**
Label Claim	Each vial contains: Moroctocog Alfa... 500 IU
Reference to Finished product specifications	European Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	3 Year(s)2-8 °C
For generic drugs (me-too Status)	No recombinant factor VIII registered yet
Pharmacotherapeutic Group of (API)	Antihemophilic factor (recombinant) ATC Code: B02BD02
Name, address of Manufacturing site:	Saman Daroo 8-Khorasan Science and Technology Park, Mashhad-Iran
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	Saman Daroo 8, Khorasan Science and Technology Park, Mashhad, Iran
Details of Certificates (CoPP/FSC/cGMP):	Ministry of Foreign Affairs attested COPP No. 665/79752 dated 27-01-2026 is attached.
Details of Authorization Letter :	LOA No. 102/1656 dated 07-01-2026 attached with 3 years validity.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The bulk was stored at 4°C and tested at the 12, 24 and 48 hours after production. Accelerated testing was carried out at 25°C for 4 hours.
The status in reference regulatory authorities	XYNTHOPHILIA

Evaluation Remarks

Certain queries were communicated to the applicant. The applicant has submitted responses to these queries, which are presented in the table below;

S.No.	Queries	Response	Remarks
1	COPP not legalized. Submit valid legalized COPP.	Attached as Annex-VI	Ministry of Foreign Affairs attested COPP attached.
2	Module 3.2.S.7 (stability of drug substance) is not provided.	Attached as Annex-VII	The bulk was stored at 4°C and tested at the 12, 24 and 48 hours after production. Accelerated testing was carried out at 25°C for 4 hours.
3	Real time and accelerated stability of drug product on 3 commercial batches on Zone IVa conditions is required.	Attached as Annex-VIII	All parameters as per Ph.Eur are not tested.

4	Bio similarity data as per WHO Bio similarity guidelines in tabular form is required including;		
	Ø Comparative structural and functional characterization with the Reference product.	Attached As Annex-l	Complete physicochemical and structural characterization is still required.
	Ø Comparative in vitro bioassays for receptor affinity and activation.	Technical documentation of the product is available in our company since it entered the clinical phase. In-Vitro research dates back a decade ago and was done in a university laboratory, and we do not have access to it.	Not provided.
	Ø Comparative in-vivo potency.	We do not have comparative in-vivo potency reports. Please pay attention our Product has been used in Iran for many years and no specific side effects have been observed in clinical studies or during these years. Moreover, Safacto is also approved by the International Society of Hematology.	Not provided.
	Ø Impurity testing (product related and process related).	Attached as Annex-II	Comparative impurity testing with innovator is not provided.
	Ø Comparative Pharmacokinetic studies	Attached as Annex-III At the time of the initial tests,	Comparative PK studies are not conducted.

		Xyntha product was not available in the country due to the sanctions, and therefore these studies were not conducted in a comparative manner. However, the Pharmacokinetic studies on our product are available.	
	Ø Comparative Toxicology studies (single dose and repeat dose).	Attached as Annex-IV Our product is biosimilar of Xyntha, it toxicological studies are also consistent and approved for our product. Our Product has been used in Iran for many years and no specific side effects have been observed in clinical studies or during these years. Moreover, Safacto is also approved by the International Society of Hematology.	Comparative toxicology studies are not conducted.
	Ø Comparative Clinical trial study reports as per EMA guideline "Guideline on the clinical investigation of recombinant and human plasma-derived factor VIII products" including Efficacy in PTPs ≥12 years and Clinical investigation in children <12 years and Clinical investigation in PUPs as well as immunogenicity studies.	Attached as Annex-V Efficacy PTP >12 years ---> Report 2, page 45 and the result on page 62. Clinical investigation In PUPs ---> Is not available, since the product must be used after the patient has history of more than 50 days of exposure to FVIII, and in IRAN this process is mandatory. Immunogenicity studies ---> The inhibitory tests to investigate Immunogenicity have been done on the patients during the clinical trial study. This investigation has been done in the same clinical trial study on adults (age 4-43). Moreover, the	The firm has submitted single page summary of PK study conducted in 24 Hemophilia A patients (including 10 children and 14 adults). Firm has also submitted following study; "A Comparative Study of Efficacy, Safety and Immunogenicity of Recombinant Coagulation Factor VIII (Safacto) with Xyntha Recombinant Factor VIII in Patients with Severe Hemophilia A with a History of More Than 50 Days of Previous Exposure to Coagulation Factor in the Form of Multicenter in Iran" This study was performed on 33 patients (16 people used Xyntha and 17 people

		product has been used by children in Iran for several years and also in Syria and Sri Lanka, without any written compliment.	used Safacto). The average age of Xyntha and Safacto users was 16 and 19 years. However as per EMA guidelines; "Guideline on the clinical investigation of recombinant and human plasma-derived factor VIII products" Efficacy in PTPs ≥12 years (at least 50PTPs) and Clinical investigation in children <12 years (at least 50 children) is required as pre-authorization requirement.

Decision of 360th meeting: Registration Board deferred the case for submission of following documents/clarifications; Complete comparative physicochemical and structural characterization of the applied product against the reference product. Comparative in vitro bioassays for receptor affinity and activation relative to the reference product. Comparative impurity profile analysis with the innovator/reference product. Comparative non-clinical toxicology studies conducted against the reference product. Clinical study data generated in accordance with the applicable EMA Guideline on Factor VIII Products.

S.No.	Queries	Response
1	Complete comparative physicochemical and structural characterization of the applied product against the reference product.	For Structural characterization of Safacto AF reference product reducing and non-reducing PAGE (Gel Electrophoresis), Western blot ar isoelectric focusing (IEF), peptide mapping u Results of scans Attached as Annex-1physicochemical characterization of Safacto attached in Annex-1 on Page.18, which are comparable with reference product.Chromato characterization of Structure and impurity ve

			of Safacto AF and reference product also atta Annexure-2 and results of both products.
	2	Comparative in vitro bioassays for receptor affinity and activation relative to the reference product.	The biological activity and potency of Safact have been evaluated using validated chromo assay calibrated against the Biological Refer Preparation (BRP) obtained from EDQM. Al dedicated head-to-head comparative in vitro bioassays for receptor affinity and activation performed, the submitted analytical characte potency evaluation, and impurity assessment collectively support the quality, consistency, biological activity of Safacto AF. The attache comparative analytical reports are submitted consideration. All analytical and quality eval were performed in accordance with applicab regulatory requirements and approved by the Food and Drug Administration (IFDA).Justif Letter from Safacto AF Manufacturer is attac Annexure-3
	3	Comparative impurity profile analysis with the innovator/reference product.	Impurity Testing of Safacto AF for impuritiesMolecular Weight Distribution (Ag form), Related protein (Oxidized form), Hos Protein, Host Cell DNA and Endotoxin Cont been performed. Analysis Results are attache Annexure-4However Chromatographic characterization of impurity testing of Safact reference product were performed and attach Annexure-2 and results of both products are comparable.
	4	Comparative non-clinical toxicology studies conducted against the reference product.	The available pharmacokinetic and toxicolog vivo potency studies were conducted during development of Safacto AF and were not des head-to-head comparative studies with Xynth studies were performed in accordance with th applicable requirements of the Iran Food and Administration, and the results were reviewe accepted by the Ministry of Health Iran. A comparative assessment of the available pharmacokinetic data for Safacto AF and the reference product, Xyntha, is attached for rev (Annexure-5 attached) Additionally, the para Half-life, AUC, and In-Vivo Recovery are pr comparatively in the same file for the assessr in vivo potency. Safacto AF has been market Iran for several years and has also been expo Sri Lanka and Syria. No specific safety conc been identified during clinical studies or pos marketing use. Safacto AF is also listed in th Federation of Hemophilia (WFH) treatment database.Manufacturer Justification Letter A as Annexure-6.
	5	Clinical study data generated in accordance with the applicable EMA Guideline on Factor VIII Products.	The required sample size of 33 patients for C study was calculated in SPSS software and subsequently approved by the Iran FDA and Based on these results, the manufacturing an marketing authorization for industrial-scale production of Safacto was dully issued by FI

			Iran.Justification Letter from Manufacturer i attached as annexure-7 Furthermore, Safacto in the International Society of Hematology a Safacto AF is exported by Saman Daroo 8 B many other countries including Syria, Sri La Argentina, Peru, Bolivia and Azerbaijan.List Federation of Hemophilia (WFH) is attached Annexure-8 including Safacto AF by Saman Biotech.
	The firm further informed that the applied product Safacto AF is listed in the World Federation of Hemophilia (WFH) Online Clotting Factor Concentrate (CFC) Registry. The product is traceable and publicly searchable through the official WFH portal at: https://elearning.wfh.org/resource/online-cfc-registry/		
	Decision		
	Deferred **Registration Board deferred the case for submission of detailed information on the criteria and basis for inclusion of the product in the WFH CFC Registry, particularly regarding the extent to which its quality, safety, and efficacy are assessed prior to listing.**		
7	Case Category	Routine (Anam Saeed)	
	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	(QUS-Q9V-PZH2, 2026-06-18)	
	Detail of Fee Submitted	75000, 2026-05-21,	
	The proposed proprietary name / brand name	**Cy-Tb (Injectable, Solution for Injection), 1ml (10 dose vial)**	
	Label Claim	Cy-Tb 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*** ***Produced in Lactococcus lactis cells Multidose vial. One vial (1 mL) contains 10 doses of 0.1 mL.	
	Reference to Finished product specifications	Any Other	
	Proposed Pack Size	1ml / 10 dose vial-Controlled	
	Shelf Life (Unit)	3 Year2°C–8°C	
	For generic drugs (me-too Status)	N/A	
	Pharmacotherapeutic Group of (API)		
	Name, address of Manufacturing site:	Serum Institute of India Pvt. Ltd.-S.Nos. 203-205, 212, 223, 268 – 270 (H) &, 104-110 ,113-114 ,168-170 (M), HADAPSAR Pune- 411 0028, INDIA.-India	
	Pharmaceutical Equivalence and Comparative Dissolution Profile		
	Name, address of Marketing Authorization Holder:	Serum Institute of India Pvt. Ltd., S.Nos. 203-205, 212, 223, 268 – 270 (H) &, 104-110 ,113-114 ,168-170 (M), HADAPSAR Pune- 411 0028, INDIA., India	
	Details of Certificates (CoPP/FSC/cGMP):		
	Details of Authorization Letter :		

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	WHO PQ product
	Evaluation Remarks	
	The applied product is WHO Prequalified with WHO Ref. No. BT-DX001. The address of manufacturer as per WHO database is; Serum Institute of India Pvt. Ltd. 212/2 Off Soli Poonawala Road, Hadaspar Pune, Maharashtra 411 028 India. However, the address of manufacturer as per dossier is; M/s Serum Institute of India Pvt. Ltd. S.Nos. 203-205, 212, 223, 268 – 270 (H) &, 104-110 ,113-114 ,168-170 (M), HADAPSAR Pune- 411 0028, INDIA. The applicant submitted a justification that "In the registration dossier we have stated our amended address after merger of Hadapsar and Manjari premises. The same address will be updated in WHO PQ database once we received EMA (SRA) GMP renewal as our Cy-Tb WHO PQ is based on approval from SRA."	
	Decision	
	Approved Keeping in view the WHO Prequalification; Registration Board approved the product subject to: 1. Compliance of current Import Policy for finished drugs and verification of address of manufacturer from WHO database. 2. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 3. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 4. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
8	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Titlis Pharma (Private) Limited** 528-A Sundar Industrial Estate, Lahore **(05-352-0066-035681D)**
	Application Form Dy. No / Tracking ID & date of submission	(EQJ-P1P-24DV, 2025-08-21)
	Detail of Fee Submitted	313500.0, 2025-08-15,
	The proposed proprietary name / brand name	**GerEpo 10000IU Vial**
	Label Claim	Each Vial contains: Recombinant Human Erythropoietin....10000IU
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's -Controlled,10's-Controlled
	Shelf Life (Unit)	2 Year(s)2°C-8°C
	For generic drugs (me-too Status)	Epiao (10000IU/ml) 1 Vial Injection
	Pharmacotherapeutic Group of (API)	Therapeutic biological product WHO ATC code: B03XA01
	Name, address of Manufacturing site:	NCPC Genetech Biotechnology Co., Ltd-No.106 Tianshan South Street, High & New Technology Industries Development Zone, Shijiazhuang-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity with Eprex
	Name, address of Marketing Authorization Holder:	NCPC Genetech Biotechnology Co., Ltd, No.106 Tianshan South Street, High & New Technology

	Industries Development Zone, Shijiazhuang, China
Details of Certificates (CoPP/FSC/cGMP):	Apostile COPP No.Hebei20250342 dated 24-06-2025 valid till 23-06-2027
Details of Authorization Letter :	Apostile Sole Agency agreement dated 11-02-2025
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	EPOGEN/PROCRIT (USFDA Approved)

Evaluation Remarks

Certain queries were raised with the applicant, to which they submitted the following reply:

Sr.No.	Queries	Response	Remarks
1	Submit revised module 1 as per updated CTD Guidance document.	We updated the Module 1, please refer to "Module 1- update".	Submitted
2	Shelf life is mentioned as 36 months in SmPC while the stability data is submitted till 24 months and shelf life mentioned in application is also 24 months.	So far, the shelf life of Human Erythropoietin Injection has 36 months data of long term stability study, and the 36 months shelf life has been approved by NMPA of China. The detailed information, please refer to: Annex 2-1: 3.2.P.8 Stability 36 months - EPO Injection PFS Annex 2-2: 3.2.P.8 Stability 36 months - EPO Injection Vial Annex 2-3: Approval notice for 36 months shelf life by China NMPA So, the proposed shelf life of Human Erythropoietin Injection was 36 months.	Pre-registration variation fee is not submitted.
3	Separate COPPs are required for vial and PFS.	Justification letter from manufacturer attached.	Manufacturer has provided drug registration certificate where both pack sizes are mentioned under same registration number.
4	The applicant should submit at least 12-month immunogenicity data pre-authorisation as per EMA "Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant erythropoietins".	1)The Phase III clinical trial of EPO was conducted in Malaysia during 2005 to 2006, "A Randomized, Multi-center, Open label trial to establish the therapeutic equivalence between GerEPO and Eprex in patients on Hemodialysis by intravenous route", the immunogenicity was studies in the trail, but the number of adverse events reported and the 3-month trial was too short to allow any definitive conclusion. There is however no obvious trend of greater AEs being associated with GerEPO treatment, nor is there any apparent signal to indicate that patients should not be exposed to GerEPO to allow its long term safety profile be better established through pharmaco-vigilance means. So far, NCPC Genetech Biotechnology Co., Ltd. did not conduct separately clinical trial to collect 12-month immunogenicity data 2)In order to	Immunogenicity is not performed during clinical trial. Report of Post-marketing Clinical Immunogenicity of EPO Injection produced by NCPC Genetech Biotechnology Co., Ltd. is provided from 2000 to the end of 2019 while the applied strength is not included in that report.

			investigate the post-marketing safety of Human Erythropoietin Injection produced by NCPC Genetech Biotechnology Co., Ltd., especially focus on the investigation of immunogenicity related ADRs such as pure red aplastic anemia (PRCA), we are going to keep to collect safety reports of immunogenicity and other adverse drugs reactions, then investigate, analyze and detect the cases data with suspected PRCA. The safety data of immunogenicity and other ADRs were collected from the post-marketing of 2000 to the end of 2019, and conduct summarizing and classification. Estimate the patient quantity exposure to EPO via the annual cumulative sales volume of each strength. The incidence rate of immunogenicity and other safety data were calculated by the cases collected and the estimated quantity. The safety investigation results of immunogenicity related to EPO were evaluated. During the reporting period, this product did not experience any serious immunogenicity related adverse reactions such as PRCA. The incidence of other types of adverse reactions was relatively low, and the cumulative systemic organ damage was extremely rare. From the above safety information data, it can be seen that the recombinant human erythropoietin of NCPC Genetech Biotechnology Co., Ltd. has good safety. We will continue to collect safety reports on immunogenicity and others, and further investigation, analysis, and testing will be conducted on suspected cases of adverse reactions such as PRCA.	
5	Since pharmacokinetics and dose requirements usually differ for IV and SC use, similar efficacy between the test and the reference product should be ensured for both routes of administration. Similar efficacy for both routes of administration may be demonstrated by performing two separate clinical trials as per EMA "Guideline on non-clinical and clinical development of	EPO Injection produced by NCPC Genetech Biotechnology Co., Ltd. has been approved for three indications, and for each indication, there are different routes of administration, which are consistent with the reference product and are described in the instructions (Packaging Insert). Corresponding clinical trials have been conducted for the corresponding routes of administration. 1)For renal anemia, there are two administration routes, intravenous injection and subcutaneous injection, with the same administration method as the reference product. The clinical trial report can be found in: Annex 5-1: Phase II clinical trial of EPO in China (1998-2000) Annex 5-2: Phase III clinical trial of EPO in Malaysia (2005-2006) Annex 5-3: Phase III Clinical trial of EPO in Indonesia (2017-2018) 2)For anemia caused by tumor chemotherapy, the administration route is subcutaneous injection. The clinical trial	Clinical trials provided by the manufacturer are listed below this table.

	similar biological medicinal products containing recombinant erythropoietins".	report is attached in Annex 5-4: Phase III Clinical Trial of EPO on Anemia Caused by Tumor Chemotherapy in China (2010-2012) 3) For the mobilization of red blood cells during the perioperative period of surgery, the administration route is subcutaneous injection. The clinical trial report is attached in Annex 5-5: Phase III Clinical Trial of EPO in China (2018-2021)	
6	Route of administration should be clearly mentioned in SmPC.	The “Route of Administration” was descripted in the SmPC update, showed in the yellow content, please refer to Annex 6: 1.5.14.1 Summary of Product Characteristics (SmPC) update. [Route of Administration] 1. Renal anemia: subcutaneous injection or intravenous injection 2. Anemia caused by tumor chemotherapy: subcutaneous injection 3. Red blood cell mobilization during the perioperative period of surgery: subcutaneous injection	Submitted

Clinical studies:

No.	Type of study	Studies
1	Phase I in China	Single center, phase 1, double-blind, randomized, and single dose intravenous administration pharmacokinetics (PK) of EPO (NCPC) and reference ESPO (Kyowa Kirin Co., Ltd.) in healthy volunteers
2	Phase II in China	Recombinant Human Erythropoietin Injection Clinical Confirmatory Trial, Non-blind randomized control trial and the non-blind non-control trial between the rhEPO (NCPC) and reference ESPO (Kyowa Kirin Co., Ltd.) by intravenous and subcutaneous route in patients with anemia caused by chromanic kidney disease by intravenous and subcutaneous routes
3	Phase III in Malaysia	A Randomized, Multi-center, Open label trial to establish the therapeutic equivalence between GerEPO™ and Eprex in patients on Hemodialysis Investigational Product: GerEpo injection, containing recombinant human erythropoietin 2000 Units in pre-filled syringe Reference Product: Eprex® injection, containing recombinant human erythropoietin 2000 Units/0.5 ml in prefilled syringe. Study period (months): 6 months 188 patients on Hemodialysis from 30 participating sites who meet inclusion/ exclusion criteria were enrolled into the trial. Duration of treatment: 12 weeks Mode of Administration: Intravenous Injection
4	Phase III in China	A Randomized, Single-Blind, Positive Drug Parallel Control and MultiCentre Clinical Trial on Anemia Caused by Tumor Chemothepray with EPO 0.5ml:12000IU by subcutaneous route. Test group 1: Recombinant Human Erythropoietin Injection (Jimaixin) 12000 IU/vial, 150IU/kg each time, three times a week, subcutaneous injection for 8 consecutive weeks. Test group 2: Recombinant Human Erythropoietin Injection (Jimaixin) 24000 IU/vial, three times a week, 150IU/kg each time, subcutaneously injected for 8 consecutive weeks. Control group Recombinant Human Erythropoietin Injection (EPIAO) 10000 IU/vial, three times a week, 150IU/kg each time, subcutaneously injected for 8 consecutive weeks. No. of subjects: Planned 228 cases, actually 216 cases Treatment duration 8 weeks

5	Phase III in Indonesia	Clinical Comparison of Renogen, a Biosimilar Epoetin-α, with the Originator Eprex in Chronic Kidney Disease (CKD) Anemia: A Confirmatory Study (a maintenance phase study) in Indonesia Population. Aim: To compare efficacy and tolerance of Renogen with Eprex in CKD anemia. Route of administration: Intravenous No. of subjects: Total 45 patients, in which, 30 patients received Renogen and 15 patients received Eprex. Treatment duration: 12 weeks
6	Phase III in China	A randomized, single blind, positive drug, parallel controlled, multicenter clinical trial of recombinant human erythropoietin injection (CHO cells) (1ml:10000IU) for perioperative red blood cell mobilization in surgery Route of Administration: Subcutaneous No. of subjects: 158 cases were randomized into the groups, 80 cases in the test group and 78 cases in the control group. Treatment duration: Two weeks in total (6 medications) Test drug: Recombinant Human Erythropoietin Injection (CHO cell); strength: 1 ml: 10000 IU; batch No.: S201805YJ01/S202002YJ01; manufactured by NCPC Genetech Biotechnology Co., Ltd. Reference Drug: Recombinant Human Erythropoietin Injection (CHO cell); Trade name: Yibiao; Strength: 1 ml: 10000 IU; batch No.: 201712220S/201712234S/201805092S/201908153S/201912238S; manufactured by Shenyang Sunshine Pharmaceuticals CO., Ltd. China.

The trial conducted to assess the applied strength is mentioned at Sr. No. 06 above; however, the comparator product used in the trial is not a reference product.

Decision

Approved

Registration Board approved the product subject to:

1. Compliance of current Import Policy for finished drugs.

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

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

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

9		
	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Titlis Pharma (Private) Limited** 528-A Sundar Industrial Estate, Lahore **(05-352-0066-035681D)**
	Application Form Dy. No / Tracking ID & date of submission	(GDL-MGU-1HGS, 2025-08-21)
	Detail of Fee Submitted	313500.0, 2025-08-15,
	The proposed proprietary name / brand name	**GerEpo 10000IU Pre Filled Syringe**
	Label Claim	Each Pre Filled Syringe contains: Recombinant Human Erythropoietin....10000IU
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's -Controlled,10's -Controlled
	Shelf Life (Unit)	2 Year(s)2°C-8°C
	For generic drugs (me-too Status)	Eprex from Janssen-Cilag Ltd.
	Pharmacotherapeutic Group of (API)	Therapeutic biological product ATC: B03XA01
	Name, address of Manufacturing site:	NCPC Genetech Biotechnology Co., Ltd-No.106 Tianshan South Street, High & New Technology

	Industries Development Zone, Shijiazhuang-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilar to Eprex
Name, address of Marketing Authorization Holder:	NCPC Genetech Biotechnology Co., Ltd, No.106 Tianshan South Street, High & New Technology Industries Development Zone, Shijiazhuang, China
Details of Certificates (CoPP/FSC/cGMP):	Apostile COPP No.Hebei20250342 dated 24-06-2025 valid till 23-06-2027
Details of Authorization Letter :	Apostile Sole Agency agreement dated 11-02-2025
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	EPOGEN/PROCRIT (USFDA Approved)

Evaluation Remarks

Certain queries were raised with the applicant, to which they submitted the following reply:

Sr.No.	Queries	Response	Remarks
1	Submit revised module 1 as per updated CTD Guidance document.	We updated the Module 1, please refer to "Module 1- update".	Submitted
2	Shelf life is mentioned as 36 months in SmPC while the stability data is submitted till 24 months and shelf life mentioned in application is also 24 months.	So far, the shelf life of Human Erythropoietin Injection has 36 months data of long term stability study, and the 36 months shelf life has been approved by NMPA of China. The detailed information, please refer to: Annex 2-1: 3.2.P.8 Stability 36 months - EPO Injection PFS Annex 2-2: 3.2.P.8 Stability 36 months - EPO Injection Vial Annex 2-3: Approval notice for 36 months shelf life by China NMPA So, the proposed shelf life of Human Erythropoietin Injection was 36 months.	Pre-registration variation fee is not submitted.
3	Separate COPPs are required for vial and PFS.	Justification letter from manufacturer attached.	Manufacturer has provided drug registration certificate where both pack sizes are mentioned under same registration number.
4	The applicant should submit at least 12-month immunogenicity data pre-authorisation as per EMA "Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant erythropoietins".	1)The Phase III clinical trial of EPO was conducted in Malaysia during 2005 to 2006, "A Randomized, Multi-center, Open label trial to establish the therapeutic equivalence between GerEPO and Eprex in patients on Hemodialysis by intravenous route", the immunogenicity was studies in the trail, but the number of adverse events reported and the 3-month trial was too short to allow any definitive conclusion. There is however no obvious trend of greater AEs being associated with GerEPO treatment, nor is there any apparent signal to indicate that patients should not be exposed to GerEPO to	Immunogenicity is not performed during clinical trial. Report of Post-marketing Clinical Immunogenicity of EPO Injection produced by NCPC Genetech Biotechnology Co., Ltd. is provided from 2000 to the end of 2019 while the applied

			allow its long term safety profile be better established through pharmaco-vigilance means. So far, NCPC Genetech Biotechnology Co., Ltd. did not conduct separately clinical trial to collect 12-month immunogenicity data 2)In order to investigate the post-marketing safety of Human Erythropoietin Injection produced by NCPC Genetech Biotechnology Co., Ltd., especially focus on the investigation of immunogenicity related ADRs such as pure red aplastic anemia (PRCA), we are going to keep to collect safety reports of immunogenicity and other adverse drugs reactions, then investigate, analyze and detect the cases data with suspected PRCA. The safety data of immunogenicity and other ADRs were collected from the post-marketing of 2000 to the end of 2019, and conduct summarizing and classification. Estimate the patient quantity exposure to EPO via the annual cumulative sales volume of each strength. The incidence rate of immunogenicity and other safety data were calculated by the cases collected and the estimated quantity. The safety investigation results of immunogenicity related to EPO were evaluated. During the reporting period, this product did not experience any serious immunogenicity related adverse reactions such as PRCA. The incidence of other types of adverse reactions was relatively low, and the cumulative systemic organ damage was extremely rare. From the above safety information data, it can be seen that the recombinant human erythropoietin of NCPC Genetech Biotechnology Co., Ltd. has good safety. We will continue to collect safety reports on immunogenicity and others, and further investigation, analysis, and testing will be conducted on suspected cases of adverse reactions such as PRCA.	strength is not included in that report.
5	Since pharmacokinetics and dose requirements usually differ for IV and SC use, similar efficacy between the test and the reference product should be ensured for both routes of administration. Similar efficacy for both routes of administration may be demonstrated by	EPO Injection produced by NCPC Genetech Biotechnology Co., Ltd. has been approved for three indications, and for each indication, there are different routes of administration, which are consistent with the reference product and are described in the instructions (Packaging Insert). Corresponding clinical trials have been conducted for the corresponding routes of administration. 1)For renal anemia, there are two administration routes, intravenous injection and subcutaneous injection, with the same administration method as the reference product. The clinical trial report can be found in: Annex 5-1: Phase II clinical trial of EPO in China (1998-2000) Annex 5-2:	Clinical trials provided by the manufacturer are listed below this table.

	performing two separate clinical trials as per EMA "Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant erythropoietins".	Phase III clinical trial of EPO in Malaysia (2005-2006) Annex 5-3: Phase III Clinical trial of EPO in Indonesia (2017-2018) 2)For anemia caused by tumor chemotherapy, the administration route is subcutaneous injection. The clinical trial report is attached in Annex 5-4: Phase III Clinical Trial of EPO on Anemia Caused by Tumor Chemotherapy in China (2010-2012) 3) For the mobilization of red blood cells during the perioperative period of surgery, the administration route is subcutaneous injection. The clinical trial report is attached in Annex 5-5: Phase III Clinical Trial of EPO in China (2018-2021)	
6	Route of administration should be clearly mentioned in SmPC.	The “Route of Administration” was descripted in the SmPC update, showed in the yellow content, please refer to Annex 6: 1.5.14.1 Summary of Product Characteristics (SmPC) update. [Route of Administration] 1. Renal anemia: subcutaneous injection or intravenous injection 2. Anemia caused by tumor chemotherapy: subcutaneous injection 3. Red blood cell mobilization during the perioperative period of surgery: subcutaneous injection	Submitted

Clinical studies:

No.	Type of study	Studies
1	Phase I in China	Single center, phase 1, double-blind, randomized, and single dose intravenous administration pharmacokinetics (PK) of EPO (NCPC) and reference ESPO (Kyowa Kirin Co., Ltd.) in healthy volunteers
2	Phase II in China	Recombinant Human Erythropoietin Injection Clinical Confirmatory Trial, Non-blind randomized control trial and the non-blind non-control trial between the rhEPO (NCPC) and reference ESPO (Kyowa Kirin Co., Ltd.) by intravenous and subcutaneous route in patients with anemia caused by chromanic kidney disease by intravenous and subcutaneous routes
3	Phase III in Malaysia	A Randomized, Multi-center, Open label trial to establish the therapeutic equivalence between GerEPO™ and Eprex in patients on Hemodialysis Investigational Product: GerEpo injection, containing recombinant human erythropoietin 2000 Units in pre-filled syringe Reference Product: Eprex® injection, containing recombinant human erythropoietin 2000 Units/0.5 ml in prefilled syringe. Study period (months): 6 months 188 patients on Hemodialysis from 30 participating sites who meet inclusion/ exclusion criteria were enrolled into the trial. Duration of treatment: 12 weeks Mode of Administration: Intravenous Injection
4	Phase III in China	A Randomized, Single-Blind, Positive Drug Parallel Control and MultiCentre Clinical Trial on Anemia Caused by Tumor Chemothepray with EPO 0.5ml:12000IU by subcutaneous route. Test group 1: Recombinant Human Erythropoietin Injection (Jimaixin) 12000 IU/vial, 150IU/kg each time, three times a week, subcutaneous injection for 8 consecutive weeks. Test group 2: Recombinant Human Erythropoietin Injection (Jimaixin) 24000 IU/vial, three times a week, 150IU/kg each time, subcutaneously injected for 8 consecutive weeks. Control group Recombinant Human Erythropoietin Injection (EPIAO) 10000 IU/vial, three times a week, 150IU/kg each time, subcutaneously injected for 8 consecutive weeks. No. of subjects: Planned 228 cases, actually 216 cases Treatment duration 8 weeks

	5	Phase III in Indonesia	Clinical Comparison of Renogen, a Biosimilar Epoetin-α, with the Originator Eprex in Chronic Kidney Disease (CKD) Anemia: A Confirmatory Study (a maintenance phase study) in Indonesia Population. Aim: To compare efficacy and tolerance of Renogen with Eprex in CKD anemia. Route of administration: Intravenous No. of subjects: Total 45 patients, in which, 30 patients received Renogen and 15 patients received Eprex. Treatment duration: 12 weeks
	6	Phase III in China	A randomized, single blind, positive drug, parallel controlled, multicenter clinical trial of recombinant human erythropoietin injection (CHO cells) (1ml:10000IU) for perioperative red blood cell mobilization in surgery Route of Administration: Subcutaneous No. of subjects: 158 cases were randomized into the groups, 80 cases in the test group and 78 cases in the control group. Treatment duration: Two weeks in total (6 medications) Test drug: Recombinant Human Erythropoietin Injection (CHO cell); strength: 1 ml: 10000 IU; batch No.: S201805YJ01/S202002YJ01; manufactured by NCPC Genetech Biotechnology Co., Ltd. Reference Drug: Recombinant Human Erythropoietin Injection (CHO cell); Trade name: Yibiao; Strength: 1 ml: 10000 IU; batch No.: 201712220S/201712234S/201805092S/201908153S/201912238S; manufactured by Shenyang Sunshine Pharmaceuticals CO., Ltd. China.

The trial conducted to assess the applied strength is mentioned at Sr. No. 06 above; however, the comparator product used in the trial is not a reference product.

Decision

Approved

Registration Board approved the product subject to:

1. Compliance of current Import Policy for finished drugs.

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

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

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

10	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	(RLQ-YXA-T5DD, 2026-06-16)
	Detail of Fee Submitted	313500, 2026-06-03,
	The proposed proprietary name / brand name	**Eyresta 40mg/ml**
	Label Claim	Each vial contains 4 mg aflibercept in 0.1 mL solution.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Month(s)Store in a refrigerator (2°C – 8°C). Do not freeze
	For generic drugs (me-too Status)	Eylea®, Registration Number: 077550, Bayer Pakistan (Private) Limited,Plot No. 23, Sector 22,

		Korangi Industrial Area (K.I.A.), Karachi, Pakistan
	Pharmacotherapeutic Group of (API)	Vascular Endothelial Growth Factor (VEGF) Inhibitor; Recombinant Fusion Protein; Anti-neovascularization Agent.
	Name, address of Manufacturing site:	Shandong Boan Biotechnology Co., Ltd.-No. 8 Kechuangxi Road, Hi-Tech Industrial Development Zone, Yantai, Shandong-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilar to Eylea
	Name, address of Marketing Authorization Holder:	Shandong Boan Biotechnology Co., Ltd., No. 39 Keji Avenue, Hi-Tech Industrial Development Zone, Yantai, Shandong, China
	Details of Certificates (CoPP/FSC/cGMP):	Firm has submitted original CoPP having certificate no. 20264110 issued by Shandong Provincial Medical Products Administration. The COPP specifies that the product is licensed for sale in country of origin. The COPP remains valid until 06/05/2029.
	Details of Authorization Letter :	Firm has submitted Apostilled Sole Agency Letter of authorization from Boan Biotechnology Co., Ltd. According to the letter, the firm Boan Biotechnology Co., Ltd exclusively authorizes "M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. for the purpose of registration, distribution and marketing of the product."
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted till 12 months
	The status in reference regulatory authorities	Eylea®,Each mL contains 40 mg Aflibercept (40 mg/mL) in a sterile, preservative-free solution for intravitreal injection.,Bayer HealthCare Pharmaceuticals Inc..)USFDA Approved
	Evaluation Remarks	
	Stability data for the drug substance of process validation batches has been submitted only up to 12 months. Similarly, Stability data of three process validation batches of drug product is submitted till 12 months only and the applicant has requested to grant approval for a 12-month shelf life for the product and stated that ongoing stability studies will continue in accordance with the approved stability protocol, and updated stability data generated during the study will be submitted to DRAP as and when available.	
	Decision	
	Approved Registration Board approved the product with a shelf life of 12 months, subject to compliance of current import policy for Finished products.	
11	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(L42-8YE-NWGM, 2026-03-12)
	Detail of Fee Submitted	38700, 2026-01-28,
	The proposed proprietary name / brand name	**T-ZEP 7.5mg/0.6ml solution for injection in multi dose cartridge**

	Label Claim	Each dose of 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 2 - 8°C
	For generic drugs (me-too Status)	Mounjaro 7.5mg/dose (30mg/2.4ml) KwikPen
	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	
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate No: RO-E8B43E dated 15-0802025 for import of 180gm of tirzepatide is provided.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative studies with Mounjaro is provided on Finished product specification parameters.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	GMP certificate was issued on 12-08-2024
	Evidence of approval of manufacturing facility	Layout plan was regularized on 14-11-2025
	Evaluation Remarks	
	In response to the query regarding the cell-based bioassay, the firm informed that the RBA (relative biological activity) test has been arranged to be performed at an outsourcing facility through M/s JB Scientific. The quotation received from M/s JB Scientific for the outsourced testing is attached. Peptide mapping by LC-MS is not performed and firm submitted a justification that "the innovator has used LCMS for peptide mapping at the time of drug development, it's important to note that LC-MS can help in the Structural elucidation which is required at the drug discovery level however for the identification of the already established products, HPLC technique is sufficient to compare peptide maps with reference standards. Additionally, HPLC methods for peptide maps are supported by several monograph in recognized pharmacopoeias (e.g. BP monograph for Human insulin, Insulin glargine etc.) where RP-HPLC based peptide mapping is included as an identification test and also Innovator perform Peptide mapping of Drug product by RP-HPLC".	
	Decision	
	Approved Registration Board approved the product subject to: 1. Submission of cell-based bioassay report. 2. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 3. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 4. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
12	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**

Application Form Dy. No / Tracking ID & date of submission	(SX9-MWQ-J16B, 2026-02-24)
Detail of Fee Submitted	38700, 2026-01-28,
The proposed proprietary name / brand name	**T-ZEP 2.5mg/0.6ml solution for injection in multi dose cartridge**
Label Claim	Each dose of 0.6ml contains: Tirzepatide ..... 2.5mg Innovator's Specs
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1s-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at 2-8°C
For generic drugs (me-too Status)	Mounjaro KwinkPen, Eli Lilly Pakistan
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	
Detail of stability batches of drug product	Submitted
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate No: RO-E8B43E dated 15-0802025 for import of 180gm of tirzepatide is provided.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative studies with Mounjaro is provided on Finished product specification parameters.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	MHRA
GMP status of the firm	GMP certificate was issued on 12-08-2024
Evidence of approval of manufacturing facility	Layout plan was regularized on 14-11-2025

Evaluation Remarks

In response to the query regarding the cell-based bioassay, the firm informed that the RBA (relative biological activity) test has been arranged to be performed at an outsourcing facility through M/s JB Scientific. The quotation received from M/s JB Scientific for the outsourced testing is attached. Peptide mapping by LC-MS is not performed and firm submitted a justification that "the innovator has used LCMS for peptide mapping at the time of drug development, it's important to note that LC-MS can help in the Structural elucidation which is required at the drug discovery level however for the identification of the already established products, HPLC technique is sufficient to compare peptide maps with reference standards. Additionally, HPLC methods for peptide maps are supported by several monograph in recognized pharmacopoeias (e.g. BP monograph for Human insulin, Insulin glargine etc.) where RP-HPLC based peptide mapping is included as an identification test and also Innovator perform Peptide mapping of Drug product by RP-HPLC".

Decision

Approved

Registration Board approved the product subject to:

1. Submission of cell-based bioassay report.

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

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

	4. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
13	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(T7S-85B-UXJ6, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-01-28,
	The proposed proprietary name / brand name	**T-ZEP 7.5mg/0.6ml solution for in pre-filled multidose pen**
	Label Claim	Each dose of 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 2 - 8°C
	For generic drugs (me-too Status)	Mounjaro 7.5 mg solution for injection in pre-filled pen
	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	
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate No: RO-E8B43E dated 15-0802025 for import of 180gm of tirzepatide is provided.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative studies with Mounjaro is provided on Finished product specification parameters.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	GMP certificate was issued on 12-08-2024
	Evidence of approval of manufacturing facility	Layout plan was regularized on 14-11-2025
	Evaluation Remarks	
	In response to the query regarding the cell-based bioassay, the firm informed that the RBA (relative biological activity) test has been arranged to be performed at an outsourcing facility through M/s JB Scientific. The quotation received from M/s JB Scientific for the outsourced testing is attached. Peptide mapping by LC-MS is not performed and firm submitted a justification that “the innovator has used LCMS for peptide mapping at the time of drug development, it’s important to note that LC-MS can help in the Structural elucidation which is required at the drug discovery level however for the identification of the already established products, HPLC technique is sufficient to compare peptide maps with reference standards. Additionally, HPLC methods for peptide maps are supported by several monograph in recognized pharmacopoeias (e.g. BP monograph for Human insulin, Insulin glargine etc.) where RP-HPLC based peptide mapping is included as an identification test and also Innovator perform Peptide mapping of Drug product by RP-HPLC”.	
	Decision	
	Approved Registration Board approved the product subject to: 1. Submission of cell-based bioassay report.	

	2. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 3. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 4. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
14	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(8P4-M7Z-YU44, 2026-03-12)
	Detail of Fee Submitted	38700, 2026-01-28,
	The proposed proprietary name / brand name	**T-ZEP 5mg/0.6ml solution for in pre-filled multidose pen**
	Label Claim	Each dose of 0.6ml contains: Tirzepatide 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 2 - 8°C
	For generic drugs (me-too Status)	Mounjaro 5mg/dose (30mg/2.4ml) KwikPen
	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	
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate No: RO-E8B43E dated 15-0802025 for import of 180gm of tirzepatide is provided.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative studies with Mounjaro is provided on Finished product specification parameters.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	GMP certificate was issued on 12-08-2024
	Evidence of approval of manufacturing facility	Layout plan was regularized on 14-11-2025
	Evaluation Remarks	
	In response to the query regarding the cell-based bioassay, the firm informed that the RBA (relative biological activity) test has been arranged to be performed at an outsourcing facility through M/s JB Scientific. The quotation received from M/s JB Scientific for the outsourced testing is attached. Peptide mapping by LC-MS is not performed and firm submitted a justification that "the innovator has used LCMS for peptide mapping at the time of drug development, it's important to note that LC-MS can help in the Structural elucidation which is required at the drug discovery level however for the identification of the already established products, HPLC technique is sufficient to compare peptide maps with reference standards. Additionally, HPLC methods for peptide maps are supported by several monograph in recognized pharmacopoeias (e.g. BP monograph for Human insulin, Insulin glargine etc.) where RP-HPLC based peptide mapping is included as an identification test and also Innovator perform Peptide mapping of Drug product by RP-HPLC".	
	Decision	

	Approved Registration Board approved the product subject to: 1. Submission of cell-based bioassay report. 2. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 3. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 4. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
15	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(Q8G-DHW-5NQV, 2026-03-12)
	Detail of Fee Submitted	38700, 2026-01-28,
	The proposed proprietary name / brand name	**T-ZEP 2.5mg/0.6ml solution for injection in pre-filled multi dose pen**
	Label Claim	Each dose of 0.6ml contains: Tirzepatide ..... 2.5mg Innovator's Specs.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	Mounjaro KwinkPen, Eli Lilly Pakistan
	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	
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate No: RO-E8B43E dated 15-0802025 for import of 180gm of tirzepatide is provided.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative studies with Mounjaro is provided on Finished product specification parameters.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Mounjaro 2.5 mg KwikPen solution for injection in prefilled pen, MHRA
	GMP status of the firm	GMP certificate was issued on 12-08-2024
	Evidence of approval of manufacturing facility	Layout plan was regularized on 14-11-2025
	Evaluation Remarks	
	In response to the query regarding the cell-based bioassay, the firm informed that the RBA (relative biological activity) test has been arranged to be performed at an outsourcing facility through M/s JB Scientific. The quotation received from M/s JB Scientific for the outsourced testing is attached. Peptide mapping by LC-MS is not performed and firm submitted a justification that "the innovator has used LCMS for peptide mapping at the time of drug development, it's important to note that LC-	

	MS can help in the Structural elucidation which is required at the drug discovery level however for the identification of the already established products, HPLC technique is sufficient to compare peptide maps with reference standards. Additionally, HPLC methods for peptide maps are supported by several monograph in recognized pharmacopoeias (e.g. BP monograph for Human insulin, Insulin glargine etc.) where RP-HPLC based peptide mapping is included as an identification test and also Innovator perform Peptide mapping of Drug product by RP-HPLC".	
	Decision	
	Approved Registration Board approved the product subject to: 1. Submission of cell-based bioassay report. 2. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 3. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 4. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
16	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(4BY-S2Q-ERDV, 2026-03-12)
	Detail of Fee Submitted	38700, 2026-01-28,
	The proposed proprietary name / brand name	**T-ZEP 5mg/0.5ml solution for injection in single dose vial**
	Label Claim	Each 0.5ml contains: Tirzepatide ..... 5mg Innovator's Specs.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	Yurpeak 5mg/0.5mL Vial, Eli Lilly Pakistan
	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	
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate No: RO-E8B43E dated 15-0802025 for import of 180gm of tirzepatide is provided.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative studies with Mounjaro is provided on Finished product specification parameters.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Mounjaro 5 mg solution for injection in vial, MHRA
	GMP status of the firm	GMP certificate was issued on 12-08-2024

	Evidence of approval of manufacturing facility	Layout plan was regularized on 14-11-2025
	Evaluation Remarks	
	In response to the query regarding the cell-based bioassay, the firm informed that the RBA (relative biological activity) test has been arranged to be performed at an outsourcing facility through M/s JB Scientific. The quotation received from M/s JB Scientific for the outsourced testing is attached. Peptide mapping by LC-MS is not performed and firm submitted a justification that "the innovator has used LCMS for peptide mapping at the time of drug development, it's important to note that LC-MS can help in the Structural elucidation which is required at the drug discovery level however for the identification of the already established products, HPLC technique is sufficient to compare peptide maps with reference standards. Additionally, HPLC methods for peptide maps are supported by several monograph in recognized pharmacopoeias (e.g. BP monograph for Human insulin, Insulin glargine etc.) where RP-HPLC based peptide mapping is included as an identification test and also Innovator perform Peptide mapping of Drug product by RP-HPLC".	
	Decision	
	Approved Registration Board approved the product subject to: 1. Submission of cell-based bioassay report. 2. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 3. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 4. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
17	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(UR9-WQB-2DMQ, 2026-03-12)
	Detail of Fee Submitted	38700, 2026-01-28,
	The proposed proprietary name / brand name	**T-ZEP 2.5mg/0.5ml solution for injection in single dose vial**
	Label Claim	Each 0.5ml contains: Tirzepatide ..... 2.5mg Innovator's Specs.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	Yurpeak 2.5mg/0.5mL Vial, Eli Lilly Pakistan
	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	
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate No: RO-E8B43E dated 15-0802025 for import of 180gm of tirzepatide is provided.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative studies with Mounjaro is provided on Finished product specification parameters.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Mounjaro 2.5 mg solution for injection in vial, MHRA
	GMP status of the firm	GMP certificate was issued on 12-08-2024
	Evidence of approval of manufacturing facility	Layout plan was regularized on 14-11-2025
	Evaluation Remarks	
	In response to the query regarding the cell-based bioassay, the firm informed that the RBA (relative biological activity) test has been arranged to be performed at an outsourcing facility through M/s JB Scientific. The quotation received from M/s JB Scientific for the outsourced testing is attached. Peptide mapping by LC-MS is not performed and firm submitted a justification that "the innovator has used LCMS for peptide mapping at the time of drug development, it's important to note that LC-MS can help in the Structural elucidation which is required at the drug discovery level however for the identification of the already established products, HPLC technique is sufficient to compare peptide maps with reference standards. Additionally, HPLC methods for peptide maps are supported by several monograph in recognized pharmacopoeias (e.g. BP monograph for Human insulin, Insulin glargine etc.) where RP-HPLC based peptide mapping is included as an identification test and also Innovator perform Peptide mapping of Drug product by RP-HPLC".	
	Decision	
	Approved Registration Board approved the product subject to: 1. Submission of cell-based bioassay report. 2. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 3. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 4. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
18	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(39J-YWM-MXAT, 2026-03-12)
	Detail of Fee Submitted	38700, 2026-01-28,
	The proposed proprietary name / brand name	**T-ZEP 7.5mg/0.5ml solution for injection in single dose vial**
	Label Claim	Each dose of 0.5ml contains: Tirzepatide ..... 7.5mg Innovator's Specs.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2 - 8°C
	For generic drugs (me-too Status)	Yurpeak 7.5mg/0.5mL vial - Eli Lilliy Pakistan (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate No: RO-E8B43E dated 15-0802025 for import of 180gm of tirzepatide is provided.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative studies with Mounjaro is provided on Finished product specification parameters.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	GMP certificate was issued on 12-08-2024
	Evidence of approval of manufacturing facility	Layout plan was regularized on 14-11-2025
	Evaluation Remarks	
	In response to the query regarding the cell-based bioassay, the firm informed that the RBA (relative biological activity) test has been arranged to be performed at an outsourcing facility through M/s JB Scientific. The quotation received from M/s JB Scientific for the outsourced testing is attached. Peptide mapping by LC-MS is not performed and firm submitted a justification that "the innovator has used LCMS for peptide mapping at the time of drug development, it's important to note that LC-MS can help in the Structural elucidation which is required at the drug discovery level however for the identification of the already established products, HPLC technique is sufficient to compare peptide maps with reference standards. Additionally, HPLC methods for peptide maps are supported by several monograph in recognized pharmacopoeias (e.g. BP monograph for Human insulin, Insulin glargine etc.) where RP-HPLC based peptide mapping is included as an identification test and also Innovator perform Peptide mapping of Drug product by RP-HPLC".	
	Decision	
	Approved Registration Board approved the product subject to: 1. Submission of cell-based bioassay report. 2. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 3. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 4. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
19	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(9BV-T1W-S9BE, 2026-03-12)
	Detail of Fee Submitted	38700, 2026-01-28,
	The proposed proprietary name / brand name	**T-ZEP 5mg/0.6ml solution for injection in multi dose cartridge**
	Label Claim	Each dose of 0.6ml contains: Tirzepatide .....5mg Innovator's Specs.

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	Mounjaro KwinkPen, Eli Lilly Pakistan
	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	
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate No: RO-E8B43E dated 15-0802025 for import of 180gm of tirzepatide is provided.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative studies with Mounjaro is provided on Finished product specification parameters.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Mounjaro 5 mg KwikPen Solution for Injection in prefilled pen, MHRA
	GMP status of the firm	GMP certificate was issued on 12-08-2024
	Evidence of approval of manufacturing facility	Layout plan was regularized on 14-11-2025
	Evaluation Remarks	
	In response to the query regarding the cell-based bioassay, the firm informed that the RBA (relative biological activity) test has been arranged to be performed at an outsourcing facility through M/s JB Scientific. The quotation received from M/s JB Scientific for the outsourced testing is attached. Peptide mapping by LC-MS is not performed and firm submitted a justification that "the innovator has used LCMS for peptide mapping at the time of drug development, it's important to note that LC-MS can help in the Structural elucidation which is required at the drug discovery level however for the identification of the already established products, HPLC technique is sufficient to compare peptide maps with reference standards. Additionally, HPLC methods for peptide maps are supported by several monograph in recognized pharmacopoeias (e.g. BP monograph for Human insulin, Insulin glargine etc.) where RP-HPLC based peptide mapping is included as an identification test and also Innovator perform Peptide mapping of Drug product by RP-HPLC".	
	Decision	
	Approved Registration Board approved the product subject to: 1. Submission of cell-based bioassay report. 2. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 3. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 4. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
20	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	(YYU-T7J-8GGS, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-08-01,
	The proposed proprietary name / brand name	**RYSEG 4 MG TABLET.**
	Label Claim	Each Tablet Contains: SEMAGLUTIDE.....4mg (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 25c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Semma 4 MG TABLET., DRB 361
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is placed in agenda of instant meeting for approval. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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	(XVH-PX1-D6U6, 2026-08-19)
Detail of Fee Submitted	97200, 2026-08-01,
The proposed proprietary name / brand name	**RYSEG 9 MG TABLET.**
Label Claim	Each Tablet Contains: SEMAGLUTIDE.....9mg (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore below 25c
For generic drugs (me-too Status)	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	Semma 9 MG TABLET., DRB 360
Evaluation Remarks	
The applied formulation of proposed manufacturer is already approved in 360th 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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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	(PYE-Z6X-755S, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-08-01,
	The proposed proprietary name / brand name	**RYSEG 50MG TABLET.**
	Label Claim	Each Tablet Contains: SEMAGLUTIDE.....50mg (Product complies Innovator's Specs
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	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	Semma 50 MG TABLET., DRB 360
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is already approved in 360th 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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)**
	Application Form Dy. No / Tracking ID & date of submission	(LG9-4XB-HDN8, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-08-01,
	The proposed proprietary name / brand name	**RYSEG 1.5MG TABLET.**
	Label Claim	Each Tablet Contains: SEMAGLUTIDE.....1.5mg (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 25c
	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	Semma 1.5MG TABLET., DRB 360
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is already approved in 360th 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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)**
	Application Form Dy. No / Tracking ID & date of submission	(9YH-NBR-Q875, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-08-01,
	The proposed proprietary name / brand name	**RYSEG 25 MG TABLET.**
	Label Claim	Each Tablet Contains: SEMAGLUTIDE.....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 YearStore below 25c
	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	Semma 25 MG TABLET., DRB 360
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is already approved in 360th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)**
	Application Form Dy. No / Tracking ID & date of submission	(UUV-7PZ-WVBN, 2026-07-17)
	Detail of Fee Submitted	97200, 2026-07-10,
	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 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 YearStore 2-8c
	For generic drugs (me-too Status)	Tirvox 50 mg Multi-Dose Pre-Filled Pen by Weather Folds
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Weather Folds Pharmaceuticals-Plot no. 69/2, Phase II, Industrial Area, Hattar-
	The status in reference regulatory authorities	EMA
	Detail of previous approval	MIZTIDE 50mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen, 354
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is already approved in 360th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)**
	Application Form Dy. No / Tracking ID & date of submission	(MTR-JT2-DP8U, 2026-07-17)
	Detail of Fee Submitted	97200, 2026-07-10,
	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 YearStore 2-8c
	For generic drugs (me-too Status)	Tirvox 10 mg Multi-Dose Pre-Filled Pen by Weather Folds
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Weather Folds Pharmaceuticals-Plot no. 69/2, Phase II, Industrial Area, Hattar-
	The status in reference regulatory authorities	EMA
	Detail of previous approval	MIZTIDE 10mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement	

under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.

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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)**
	Application Form Dy. No / Tracking ID & date of submission	(HXD-SDJ-AXAR, 2026-07-17)
	Detail of Fee Submitted	97200, 2026-07-10,
	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 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 YearStore 2-8c
	For generic drugs (me-too Status)	Tirvox 40 mg Multi-Dose Pre-Filled Pen by Weather Folds

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Weather Folds Pharmaceuticals-Plot no. 69/2, Phase II, Industrial Area, Hattar-
	The status in reference regulatory authorities	EMA
	Detail of previous approval	MIZTIDE 40mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen, 354
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)**
	Application Form Dy. No / Tracking ID & date of submission	(AVH-A5N-YA2L, 2026-07-17)
	Detail of Fee Submitted	97200, 2026-07-10,

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 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 YearStore 2-8c
For generic drugs (me-too Status)	Tirvox 60 mg Multi-Dose Pre-Filled Pen by Weather Folds
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	M/s Weather Folds Pharmaceuticals-Plot no. 69/2, Phase II, Industrial Area, Hattar-
The status in reference regulatory authorities	EMA
Detail of previous approval	MIZTIDE 60mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen, 354

Evaluation Remarks

The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.

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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)**
	Application Form Dy. No / Tracking ID & date of submission	(9TJ-ENE-72SU, 2026-07-17)
	Detail of Fee Submitted	97200, 2026-07-10,
	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 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 YearStore 2-8c
	For generic drugs (me-too Status)	Tirvox 20 mg Multi-Dose Pre-Filled Pen by Weather Folds
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Weather Folds Pharmaceuticals-Plot no. 69/2, Phase II, Industrial Area, Hattar-
	The status in reference regulatory authorities	EMA
	Detail of previous approval	MIZTIDE 20mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen, 354
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)**
	Application Form Dy. No / Tracking ID & date of submission	(3LV-ZNQ-GTEP, 2026-07-17)
	Detail of Fee Submitted	97200, 2026-07-10,
	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 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 YearStore 2-8c
	For generic drugs (me-too Status)	Tirvox 30 mg Multi-Dose Pre-Filled Pen by Weather Folds
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Weather Folds Pharmaceuticals-Plot no. 69/2, Phase II, Industrial Area, Hattar-
	The status in reference regulatory authorities	EMA
	Detail of previous approval	MIZTIDE 30mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen, 354
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)**
	Application Form Dy. No / Tracking ID & date of submission	(MJU-D81-QD7M, 2026-08-05)
	Detail of Fee Submitted	97200, 2026-07-30,
	The proposed proprietary name / brand name	**RYSEG Tablet 4mg**
	Label Claim	Each Tablet Contains: SEMAGLUTIDE.....4mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Semma 4mg Tablet, DRB 360
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is placed in agenda of instant meeting for approval. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of	

RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)**
	Application Form Dy. No / Tracking ID & date of submission	(PE9-1BW-X5H9, 2026-08-05)
	Detail of Fee Submitted	97200, 2026-07-30,
	The proposed proprietary name / brand name	**RYSEG Tablet 9mg**
	Label Claim	Each Tablet Contains: SEMAGLUTIDE.....9mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Semma 9mg Tablet, DRB 360
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is already approved in 360th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)**
	Application Form Dy. No / Tracking ID & date of submission	(YN3-H8G-T5M9, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-07-30,
	The proposed proprietary name / brand name	**RYSEG Tablet 25mg**
	Label Claim	Each Tablet Contains: SEMAGLUTIDE.....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 YearStore below 25°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	Semma 25mg Tablet, DRB 360
	Evaluation Remarks	

	The applied formulation of proposed manufacturer is already approved in 360th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)**
	Application Form Dy. No / Tracking ID & date of submission	(417-EGY-9M3V, 2026-08-05)
	Detail of Fee Submitted	97200, 2026-07-30,
	The proposed proprietary name / brand name	**RYSEG Tablet 1.5mg**
	Label Claim	Each Tablet Contains: SEMAGLUTIDE.....1.5mg (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)	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	Semma 1.5mg Tablet, DRB 360
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is already approved in 360th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)**
	Application Form Dy. No / Tracking ID & date of submission	(9H4-SQE-73YU, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-07-30,
	The proposed proprietary name / brand name	**RYSEG Tablet 50mg**
	Label Claim	Each Tablet Contains: SEMAGLUTIDE.....50mg (Product complies Innovator's Specs)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Semma 50mg Tablet, DRB 360
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is already approved in 360th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)**
	Application Form Dy. No / Tracking ID & date of submission	(R57-GES-6J2L, 2026-08-05)

	Detail of Fee Submitted	97200, 2025-11-14,
	The proposed proprietary name / brand name	**Terza 12.5mg Injection in PFS**
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....12.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25°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 of proposed manufacturer is already approved in 359th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)**
Application Form Dy. No / Tracking ID & date of submission	(EWU-B9R-YEB8, 2026-08-05)
Detail of Fee Submitted	97200, 2025-11-14,
The proposed proprietary name / brand name	**Terza 7.5mg Injection in PFS**
Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....7.5mg (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-De-Controlled
Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2°C – 8°C). Do not freeze
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 of proposed manufacturer is already approved in 359th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.

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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.

38	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	(9SB-E2W-88WT, 2026-08-05)
	Detail of Fee Submitted	97200, 2025-11-14,
	The proposed proprietary name / brand name	**Terza 5mg Injection in PFS**
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2°C – 8°C). Do not freeze
	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 of proposed manufacturer is already approved in 359th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.

39	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	(4NA-S8L-4DVB, 2026-08-05)
	Detail of Fee Submitted	97200, 2025-11-14,
	The proposed proprietary name / brand name	**Terza 2.5mg Injection in PFS**
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....2.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2°C – 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 of proposed manufacturer is already approved in 359th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.

40	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	(3UX-RR6-XRSU, 2026-08-05)
	Detail of Fee Submitted	97200, 2025-11-14,
	The proposed proprietary name / brand name	**Terza 15mg Injection in PFS**
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....15mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2°C – 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 of proposed manufacturer is already approved in 359th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	
41	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	(1PA-9LM-YP32, 2026-08-05)
	Detail of Fee Submitted	97200, 2025-11-14,
	The proposed proprietary name / brand name	**Terza 10mg Injection in PFS**
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....10mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator 2 °C – 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 of proposed manufacturer is already approved in 359th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of	

RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.

42	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(XUJ-P8T-BEBU, 2026-08-05)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**SEMCOM TABLET 4MG**
	Label Claim	Each Tablet Contains: SEMAGLUTIDE.....4mg (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 Year25c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Weather folds Pharmaceuticals -Plot No. 69/2, Phase-II, Industrial Area, Hattar, Haripur Haripur-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Semma 4mg Tablet, DRB361
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is placed in agenda of instant meeting for approval. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.

43	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(VEY-Y55-TJA1, 2026-08-05)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**SEMCOM TABLET 25mg**
	Label Claim	Each Tablet Contains: SEMAGLUTIDE.....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 Year25c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Weather folds Pharmaceuticals -Plot No. 69/2, Phase-II, Industrial Area, Hattar, Haripur Haripur-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Semma 25mg Tablet, DRB360
	Evaluation Remarks	

	The applied formulation of proposed manufacturer is already approved in 360th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.

44	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(N7T-PDW-QGYW, 2026-08-05)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**SEMCOM TABLET 9mg**
	Label Claim	Each Tablet Contains: SEMAGLUTIDE.....9mg (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 Year25c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	M/s Weather folds Pharmaceuticals -Plot No. 69/2, Phase-II, Industrial Area, Hattar, Haripur Haripur-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Semma 9mg Tablet, DRB360
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is already approved in 360th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	
45	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(MX5-EDX-5GD5, 2026-08-05)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**SEMMA 1.5mg Tablet**
	Label Claim	Each Tablet Contains: SEMAGLUTIDE.....1.5mg (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 Year25c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Weather folds Pharmaceuticals -Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Semma 1.5mg Tablet, DRB360
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is already approved in 360th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.	
46	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(2MH-RQW-Q1XV, 2026-08-05)
	Detail of Fee Submitted	97200, 2026-07-24,

	The proposed proprietary name / brand name	**SEMMA 50mg Tablet**
	Label Claim	Each Tablet Contains: SEMAGLUTIDE.....50mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Weather folds Pharmaceuticals -Plot No. 69/2, Phase-II, Industrial Area, Hattar, Haripur Haripur-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Semma 50mg Tablet, DRB360
	Evaluation Remarks	
	The applied formulation of proposed manufacturer is already approved in 360th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
47	Case Category	Routine (Anam Saeed)

Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
Application Form Dy. No / Tracking ID & date of submission	(XZ5-8NB-HQHP, 2026-08-05)
Detail of Fee Submitted	97200, 2025-11-13,
The proposed proprietary name / brand name	**Terza 12.5mg Injection in Prefilled Syringe**
Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....12.5mg (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-De-Controlled
Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2°C – 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 of proposed manufacturer is already approved in 359th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.

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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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 (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(XQS-1SU-EXR2, 2026-08-05)
	Detail of Fee Submitted	97200, 2025-11-13,
	The proposed proprietary name / brand name	**Terza 2.5mg Injection in Prefilled Syringe**
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....2.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator 2 °C – 8 °C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	-
	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 of proposed manufacturer is already approved in 359th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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 (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(MMR-P6U-BVAP, 2026-08-05)
	Detail of Fee Submitted	97200, 2025-11-13,
	The proposed proprietary name / brand name	**Terza 15mg Injection in Prefilled Syringe**
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....15mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2°C – 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 of proposed manufacturer is already approved in 359th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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 (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(DV4-L5P-TGXU, 2026-08-05)
	Detail of Fee Submitted	97200, 2025-11-13,
	The proposed proprietary name / brand name	**Terza 10mg Injection in Prefilled Syringe**
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....10mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator 2 °C – 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 of proposed manufacturer is already approved in 359th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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 (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(7WY-ZQH-4ZZQ, 2026-08-05)
	Detail of Fee Submitted	97200, 2025-11-13,
	The proposed proprietary name / brand name	**Terza 7.5mg Injection in Prefilled Syringe**
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....7.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2°C – 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 of proposed manufacturer is already approved in 359th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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 (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(642-UXG-TMM5, 2026-08-05)
	Detail of Fee Submitted	97200, 2025-11-13,
	The proposed proprietary name / brand name	**Terza 5mg Injection in Prefilled Syringe**
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2°C – 8°C). Do not freeze
	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 of proposed manufacturer is already approved in 359th meeting of Registration Board. The case may be approved subject to submission of of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023.	
	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 subject to submission of	

RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and 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.

53		
	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	(YTG-SE3-216Y, 2025-12-12)
	Detail of Fee Submitted	313500, 2025-12-11,
	The proposed proprietary name / brand name	**RINVAC ND+IBD+REO**
	Label Claim	Each ml of vaccine contains: Inactivated chicken Newcastle disease virus, Strain La Sota.....at least $4.0\times10^{8.0}EID_{50}$ before inactivation Inactivated infectious bursal disease virus, Strain B87.....at least $4.0\times10^{6.8}TCID_{50}$ before inactivation Inactivated Avian reovirus Strain S1133.....at least $4.0\times10^{6.2}TCID_{50}$ before inactivation
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	500ml/Bottle-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store at 2°C - 8°C
	For generic drugs (me-too Status)	Same Strains already registered in Pakistan
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Tianjin Ringpu Bio-technology Co., Ltd., Airport E-No. 168, Huanhe South Road, Airport Economic Zone, Tianjin-China

	Name, address of Marketing Authorization Holder:	Tianjin Ringpu Bio-Technology Co., Ltd., No. 1 Dongjiu Road, Tianjin Free Trade Area (Airport Economic Area), Tianjin, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille GMP Certificate No. (2022) GMP 02002 dated 25-07-2025 valid till 13-01-2027. Scanned Apostille FSC No. 2025041 dated 18-11-2025.
	Details of Authorization Letter :	Scanned Apostille Product Specific LOA valid till 03-11-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	.	
	Decision	
	Approved Keeping in view GMP and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import policy for finished drugs.	
54	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**HIPHARMA (PRIVATE) LIMITED** 123-C (FIRST FLOOR), BLOCK E, MODEL TOWN LAHORE **(05-352-0065-127168D)**
	Application Form Dy. No / Tracking ID & date of submission	(WTJ-HX1-GUNW, 2026-04-11)
	Detail of Fee Submitted	313500, 2026-04-10,
	The proposed proprietary name / brand name	**Hivac ND - Clone 30** **Newcastle Disease Vaccine, Live**
	Label Claim	Each dose contains: Newcastle disease virus, strain Clone 30.....$10^{6.0}EID_{50}$
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2000 dose/vial presentation is requested for registration.-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store between 2-8°C. Protect from light. Do not freeze
	For generic drugs (me-too Status)	Nobilis ND Clone 30 (Reg. No. 009626)
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Qixiang Biological Technology Co., Ltd-Heshuo Road 5-333 Wuzhi, Henan,-China
	Name, address of Marketing Authorization Holder:	Qixiang Biological Technology Co., Ltd, Heshuo Road 5-333 Wuzhi, Henan , China., China
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate No. (2022) GMP 16016 dated 31-03-2022 valid till 30-03-2027. FSC dated 26-03-2026.
	Details of Authorization Letter :	Apostille Agreement dated 25-02-2026.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	Fee of Rs. 9400/- for revision of specifications to Ph. Eur. specs is required.	
	Decision	

	Approved Keeping in view Apostille GMP and FSC; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of Fee of Rs. 9400/- for revision of specifications to Ph. Eur. specs.	
55	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**AL ASAR ENTERPRISES** GULSHAN E GULAB COLONY BEHIND ABDULLAH HEART CARE HOSPITAL, NEAR PULWASAL SURAJ MIANI ROAD MULTAN **(04-361-0159-96972D)**
	Application Form Dy. No / Tracking ID & date of submission	(8ZM-8QQ-ND37, 2024-10-19)
	Detail of Fee Submitted	300000.0, 2024-10-03,
	The proposed proprietary name / brand name	**ValleyVac Avian Flu H9N2**
	Label Claim	A/chicken/Eg15106VL/2015 (H9N2) of HA antigen titer not less than 9 log2 HAU Per dose
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	100ml -De-Controlled,250ml -De-Controlled,500ml-De-Controlled,50ml -De-Controlled
	Shelf Life (Unit)	2 Year(s)2-8°C
	For generic drugs (me-too Status)	JOVA ZEIT 7 Vaccine
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	M/s Egyptian Company for Biological and Pharmaceut-Block No. 101, Sixth Industrial Zone, 6 of October City Giza, Egypt.-Egypt
	Name, address of Marketing Authorization Holder:	M/s Egyptian Company for Biological and Pharmaceut, Block No. 101, Sixth Industrial Zone, 6 of October City Giza, Egypt., Egypt
	Details of Certificates (CoPP/FSC/cGMP):	Valid legalized FSC & GMP certificate has been submitted.
	Details of Authorization Letter :	Not submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Not submitted.
	Evaluation Remarks	
	The Registration Board in 347th meeting deferred the case due to following deficiencies in the application; 1. Stability studies data of three batches, has not been provided. 2. Notarized LOA from MAH, has not been provided. 3. Multiple pack sizes have been applied in a single application. The firm has now submitted the following: 1. Scanned legalized LOA along with translation. 2. Proposed Pack: 500ml 3. Stability study data of 03 batches up to the proposed shelf life.	
	Decision	
	Approved Keeping in view legalized GMP and FSC; Registration Board approved the product with pack size of 500ml subject to compliance of current Import Policy for finished drugs.	
56	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**u.m.enterprises** plot no.12 sector 15 korangi industrial area-74900 **(313)**
	Application Form Dy. No / Tracking ID & date of submission	(S4P-SBN-8SVH, 2026-01-27)

Detail of Fee Submitted	313500, 2026-01-21,
The proposed proprietary name / brand name	**PULIVAC ND Clone 30**
Label Claim	This product contains Newcastle disease virus strain Clone 30. The virus titer per dose is not less than $10^{6.0}$ EID_{50}.
Reference to Finished product specifications	Any Other
Proposed Pack Size	2000 doses/vial-De-Controlled
Shelf Life (Unit)	24 Month2-8 degree centigrade
For generic drugs (me-too Status)	Nobilis® ND Clone 30 by MSD USA distributed by Vety Care
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Pulike Biological Engineering, Inc.-No.3 Cuiwei Road, High-Tech Development Zone, Luoyang Area of China (Henan) Pilot Free Trade Zone. - China
Name, address of Marketing Authorization Holder:	Pulike Biological Engineering, Inc., No.3 Cuiwei Road, High-Tech Development Zone, Luoyang Area of China (Henan) Pilot Free Trade Zone. , China
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	

Evaluation Remarks

Registration Board in its 360th meeting deferred the case for following: 1. Comments of M/o National Food Security & Research on clinical study report submitted by the firm. 2. Evidence of Import of vaccine used in clinical trial by the firm. The response of M/o National Food Security & Research on clinical study report is still awaited. However, regarding evidence of Import of vaccine used in clinical trial by the firm, the firm has submitted the following: "This letter is in reference to the above-mentioned subject regarding the product trial sample. PULIKE Biologicals sent the PULVAC Clone 30 vaccine test sample with the complete dossiers. We sincerely apologize for any confusion or administrative delay that this process may have caused your office. It was not our intention to circumvent any protocols; rather, our company is committed in following the standard operational procedures. In order to provide complete transparency, please find enclosed the shipment tracking details for the sample and dossiers. We have attached the courier receipt and tracking history for your perusal. However, we were not able to find any specific requirements or procedures for the import of samples for clinical trials of veterinary drug products and vaccines, as there is no designated or approved institute for veterinary products similar to that established for human medicines, for which the requirements are clearly defined. We would also like to inform you that, with reference to Sindh ACT No, XXIX OD 2018, the Sindh Institute of Animal Health (SIAH) has the relevant mandate for conducting clinical trials to evaluate the safety and efficacy of veterinary products. We are fully committed to cooperating with DRAP to ensure full regulatory compliance." In this context, it is submitted that the firm submitted screenshot of online tracking of some package which is showing that package arrived at Karachi on 10-07-2025 and was in delivering status on 12-07-2025. It is for the information of the Board that the firm is claiming that this package which was arrived in Karachi on 10-07-2025 was of dossier and test sample of vaccine which was used in clinical trial conducted by the SIAH. However, the submitted clinical trial data indicates that the vial which was used in trial was of batch no. 432507003 which was manufactured on 13-07-2025. Hence, it is evident that the package arrived in Karachi on 10-07-2025 while the batch used in clinical trial was manufactured in China on 13-07-2025. The firm vide tracking ID: T5L-541-3YD9 submitted request for withdrawal of application.

Decision

Rejected

	Registration Board rejected the application as withdrawn by the firm.	
57	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(AR9-GAW-YVLM, 2025-02-20)
	Detail of Fee Submitted	37000.0, 2025-02-18,
	The proposed proprietary name / brand name	**INTERVAC ND+IB+H9 VACCINE**
	Label Claim	Each ml Contains: Inactivated Newcastle Disease (La-sota strain) virus...10^7.0 EID50, Inactivated Avian Infectious Bronchitis (H-120 strain) virus...10^6.5 EID50, Inactivated Avian Influenza (H9N2 strain) virus 10^7.0 EID50
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	300ml-De-Controlled
	Shelf Life (Unit)	1 Year(s)2-8C
	For generic drugs (me-too Status)	GPVAC ND+IB+H9 (Reg no. 084591) Grand Pharma Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhupura Road, Sheikhupura 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	
	Registration Board in its 349th meeting deferred the case for submission of following by the applicant: 1. Full descriptions of the specifications and analytical methods necessary to assure the identity, strength, quality, purity and homogeneity through out the shelf life of the drug product, is required. 2. The stability studies protocol & stability studies data of three trial batches for six months, is required to be submitted. The firm has submitted analytical methods of identity, sterility, potency, stability and safety tests. Licensing Division has communicated the decision of CLB regarding the availability of viral & bacterial vaccine sections of the firm. The Licensing division has not explained whether the above Sections are for Live vaccines or Inactivated vaccines. Moreover, they also informed that firm has applied for regularization of layout plan for which inspection shall be conducted by Licensing Division.	
	Decision	
	Approved Subject to the confirmation of section by the Licensing Division.	
58	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(RJW-3GA-B2LP, 2024-11-15)
	Detail of Fee Submitted	37000.0, 9400 2024-11-14, 2025-10-24
	The proposed proprietary name / brand name	**INTERVAC MULTICLOST VACCINE**

	Label Claim	Each Dose Contains: Clostridium perfringens (types A, B, C, D) antitoxins Alpha antitoxins.....> 4 IU/mL of rabbit serum Beta antitoxins.....> 10 IU/mL of rabbit serum Epsilon antitoxins.....> 5 IU/mL of rabbit serum Clostridium septicum antitoxins Alpha antitoxins.....> 2.5 IU/mL of rabbit serum Clostridium novyi (types A, B) antitoxins Alpha antitoxins.....> 3.5 IU/mL of rabbit serum Clostridium haemolyticum (novyi type D) Protection in guinea-pigs.....≥80% Clostridium tetani antitoxins Tetanus antitoxins.....> 2.5 IU/mL of rabbit serum Clostridium sordellii antitoxins sordellii antitoxins.....> 1.0 IU/mL of rabbit serum Clostridium chauvoei Protection in guinea-pigs.....≥90%
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled,250ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	12 Year(s)2-8C degree centigrade
	For generic drugs (me-too Status)	JOVACLOST T (Registration No. 091372) Eros Pharmaceuticals (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Veterinary Antisera
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP Certificate based on inspection dated 01-02-2024.
	Evidence of approval of manufacturing facility	Not Available.
	Evaluation Remarks	
	The applied product is included in class of Antiseras, while firm has not submitted evidence of availability of Veterinary Anti-sera Section.	
	Decision	
	Deferred For confirmation of section by the Licensing Division.	
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	(6B1-JH2-AX66, 2025-08-07)
	Detail of Fee Submitted	300000.0, 2025-07-18,
	The proposed proprietary name / brand name	**Brolizum 100 IV Infusion**
	Label Claim	Each 4ml solution contains: Pembrolizumab.....100mg

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	12 Month(s)Store at 2-8°C, protecting from light.
For generic drugs (me-too Status)	New product
Pharmacotherapeutic Group of (API)	L01FF02:Antineoplastic agents
Name, address of Manufacturing site:	Geneway Bio-Technology co., Ltd Incepta Pharma-No.6 Anmin Road, Huangdai Town, Xiangcheng, Suzhou, Jiangsu, Dewan Idris Road, Bara Rangamatia, Zirabo, Savar, Dhaka-China Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
Name, address of Marketing Authorization Holder:	Incepta Pharmaceuticals Ltd,, Dewan Idris Road, Bara Rangamatia, Zirabo,Ashulia, Savar, Dhaka-1341, Bangladesh, Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	Scanned Copy of COPP Certificate No.:DA/6-91/04/15Part-1/21842 Date: 24 Dec 2024 Validity: 2 year
Details of Authorization Letter :	Incepta Pharmaceuticals Ltd., Vaccine Division, a company duly organized under the laws of the Peoples' Republic of Bangladesh, having its main office and principal place of business at 40, Shahid Tajuddin Ahmed Sarani, Tejgaon I/A, Dhaka-1208, Bangladesh hereby certify that: M/s. Lab Diagnostic Systems (SMC) Pvt Ltd Address: 36-A,PSIC,SIE,Taxila Rawalpindi as our Exclusive distributor for the territory of Pakistan Validity: December 2026.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	FX01-2015001S FX01-2015002S FX01-2015003S 5C±3C in 0, 3th, 6th month. Below 30C in 0, 6th, 12th month.
The status in reference regulatory authorities	Keytruda Injection Manufacturer name: Merck & Co. Brand name: Keytruda Injection (also referred to as Keytruda®) Strength: 100 mg in 4 ml. This is equivalent to 25 mg/ml. Composition: The ready-to-fill bulk solution, which is similar to Keytruda, contains Pembrolizumab (as the active pharmaceutical ingredient), L- Histidine, Sucrose, Polysorbate 80, and Water for Injections as excipients. USFDA Approved

Evaluation Remarks

Registration Board in its 360th meeting directed the BE&R Division to require all applicants whose applications are currently under review to submit the following requirements: A legalized Certificate of Pharmaceutical Product (CoPP) for the finished biological drug product issued by the competent regulatory authority of the country of origin of the Ready-to-Fill (RTF) bulk manufacturer/supplier, demonstrating that the product is duly authorized for marketing and is freely sold in the country of origin. However, the requirement for submission of a CoPP may be waived by the Registration Board on a case-by-case basis, taking into consideration the public health need for the product and circumstances related to patent protection, market exclusivity, or other justified regulatory considerations. A complete Common Technical Document (CTD) dossier for the finished biological drug product manufactured by the bulk manufacturer in country of origin from the Ready-to-Fill (RTF) bulk, in accordance with WHO guidelines on biosimilarity. A comprehensive Quality Risk Management (QRM) assessment conducted in accordance with the principles outlined in ICH Q9. The assessment shall identify, evaluate, and control potential risks associated with transportation,

storage, aseptic processing, filling operations, packaging activities, environmental monitoring and control, sterility assurance, and container-closure integrity. Shipping validation and/or transportation qualification studies demonstrating that predefined storage and transportation conditions, including temperature requirements, are consistently maintained throughout the distribution process from the bulk manufacturing site to the fill-and-finish facility. Bulk holding-time studies demonstrating that storage of the bulk biological product prior to filling does not adversely affect its quality, safety, efficacy, or stability. A comparability study demonstrating that the fill-and-finish and packaging operations do not adversely impact the quality attributes of the biological drug product. The comparability exercise shall include testing of the locally filled product against both the reference product and the finished product manufactured by the RTF bulk supplier. Analytical evaluation shall include, but not be limited to, identity, protein concentration, potency, product-related impurities, aggregate content, charge variant profile, particulate matter, sterility, bacterial endotoxins, pH, and any other product-specific critical quality attributes, as applicable. Inspection of bulk manufacturer and finished product manufacturer. The firm has submitted the response which was evaluated and following are the observations: 1. CoPP is not submitted as product is not registered in China due to patent issue. 2. The drug substance part submitted by the firm is same as submitted by another firm with the name of manufacturer as M/s Intellect Bio, China. 3. The comparative characterization data submitted by the firm is of drug substance instead of finished product of ready-to-fill bulk manufacturer. 4. Quality Risk Management (QRM) assessment is not submitted. 5. Comparative study data of applied product with finished product of ready-to-fill bulk manufacturer is not submitted. 6. The clinical trial data provided does not include immunogenicity studies.

Decision

Deferred

Registration Board discussed the case in detail that data in light of decision of 360th meeting is still not completed by the firm as firm has not submitted the following:

i. CoPP issued by regulatory authority of country of origin for finished product manufactured by ready-to-fill bulk manufacturer.

ii. Batches mentioned in COAs, stability in initial dossier and in subsequent submissions are different.

iii. Comparative study data of applied product with finished product of ready-to-fill bulk manufacturer is submitted as single table without any supporting data.

iv. In clinical trials, immunogenicity studies are not performed.

The Board deliberated that CoPP of finished product manufactured by ready-to-fill bulk manufacturer is not available as the product is not registered in that country due to patent issues. Moreover, Pembrolizumab Injection is indicated in treatment of 17 cancers and is already being imported on patient need basis and the clinical trial data of this product conducted in comparison with Innovator is indicating its safety and efficacy. Hence, keeping in view the above discussion and public health need of Pembrolizumab Injection; Registration Board deferred the case and decided as follows:

In view of the substantial disease burden associated with these malignancies and the established clinical utility of Pembrolizumab in appropriately selected patients, the Board considered that the continued availability of the product may contribute to addressing an important unmet therapeutic need and facilitate patient access to an established treatment option for cancer. Furthermore, in consideration of the approval of the product by ANMAT, Argentina, the application may be processed further in accordance with the applicable regulatory requirements, subject to satisfactory assessment of the submitted quality, safety, efficacy, and Good Manufacturing Practices (GMP)-related evidence.

In view of the above, the Registration Board decided that a product-specific inspection of the overseas manufacturing facility shall be conducted to verify compliance with applicable GMP requirements and to verify the submitted data. The matter regarding the grant of Marketing Authorization (MA) shall be considered subsequently upon satisfactory confirmation of GMP compliance, along with a comprehensive evaluation and verification of the submitted technical and scientific data. The final regulatory decision shall be based on the totality of the available evidence, including the outcome of the product-specific inspection and the adequacy of the submitted quality, non-clinical, and clinical data, as well as any other information considered relevant to establishing the overall benefit-risk profile of the product.

Product specific inspection, shall be conducted by following panel of experts:

i. Two evaluators from Division of Biological Evaluation & Research, DRAP.

ii. Dr. Ali Jan, Director Drug TestingLaboratory, Quetta.

iii. Mr. Syed Adnan Rizvi, Director Drug Testing Laboratory, Karachi.

iv. Mr. Asad Abrar, Director Drug Testing Laboratory, Bahawalpur.

Firm shall submit a comprehensive Quality Risk Management (QRM) assessment conducted in accordance with the principles outlined in ICH Q9. The assessment shall identify, evaluate, and control potential risks associated with transportation, storage, aseptic processing, filling operations, packaging activities, environmental monitoring and control, sterility assurance, and container-closure integrity.

60	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	(4LS-JL6-UZSD, 2026-06-08)
	Detail of Fee Submitted	38700, 2026-03-24,
	The proposed proprietary name / brand name	**Pembrol 100mg Injection**
	Label Claim	Each vial contains Pembrolizumab 100mg/4mL
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	24 MonthStore at 2°C and 8°C
	For generic drugs (me-too Status)	Pembroxim Injection 100mg (Himmel Pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Intellective Biologics(Suzhou)Co.,Ltd. No.96,Yinhe Road,Changshou-215500,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	Keytruda 100mg Injection (MERCK & Co.,) FDA APPROVED
GMP status of the firm	
Evidence of approval of manufacturing facility	

Evaluation Remarks

Registration Board in its 360th meeting directed the BE&R Division to require all applicants whose applications are currently under review to submit the following requirements: A legalized Certificate of Pharmaceutical Product (CoPP) for the finished biological drug product issued by the competent regulatory authority of the country of origin of the Ready-to-Fill (RTF) bulk manufacturer/supplier, demonstrating that the product is duly authorized for marketing and is freely sold in the country of origin. However, the requirement for submission of a CoPP may be waived by the Registration Board on a case-by-case basis, taking into consideration the public health need for the product and circumstances related to patent protection, market exclusivity, or other justified regulatory considerations. A complete Common Technical Document (CTD) dossier for the finished biological drug product manufactured by the bulk manufacturer in country of origin from the Ready-to-Fill (RTF) bulk, in accordance with WHO guidelines on biosimilarity. A comprehensive Quality Risk Management (QRM) assessment conducted in accordance with the principles outlined in ICH Q9. The assessment shall identify, evaluate, and control potential risks associated with transportation, storage, aseptic processing, filling operations, packaging activities, environmental monitoring and control, sterility assurance, and container-closure integrity. Shipping validation and/or transportation qualification studies demonstrating that predefined storage and transportation conditions, including temperature requirements, are consistently maintained throughout the distribution process from the bulk manufacturing site to the fill-and-finish facility. Bulk holding-time studies demonstrating that storage of the bulk biological product prior to filling does not adversely affect its quality, safety, efficacy, or stability. A comparability study demonstrating that the fill-and-finish and packaging operations do not adversely impact the quality attributes of the biological drug product. The comparability exercise shall include testing of the locally filled product against both the reference product and the finished product manufactured by the RTF bulk supplier. Analytical evaluation shall include, but not be limited to, identity, protein concentration, potency, product-related impurities, aggregate content, charge variant profile, particulate matter, sterility, bacterial endotoxins, pH, and any other product-specific critical quality attributes, as applicable. Inspection of bulk manufacturer and finished product manufacturer. The firm has submitted the response which was evaluated and following are the observations: 1. CoPP is not submitted as product is not registered in China and firm has submitted following clarification: "The Drug substance supplier is based in China where the product is under patent due to which only Free sale certificate is provided. Apostilled Free Sale Certificate for Pembrolizumab is available and attached as Annexure 1 while we request a waiver for provision of COPP in line with the minutes of 360 DRB. The innovator product is not available in the country and DRAP has already issued patient need basis import license for the Finished product from Bangladesh and Russia. The aforesaid patient need base import are also manufactured with the Drug substance supplied by the same source for which we have applied for local Fill Finish registration. The Finished import on compassionate basis are being sold at hefty prices ranging from Rs.200,000 per vial to Rs.300,000 per vial which is outside the reach of almost majority of the patients. Apart from pricing challenge there is lot of cold chain issues around these Finished imports; further there are numerous counterfeed/spurious versions of these compassionate basis being unregistered imported products being sold in the market. Based on the fore mentioned facts, exemption from provision of CoPP in the country of origin for Drug substance manufacturer is requested." 2. The drug substance part submitted by the firm is same as submitted by another firm with the name of manufacturer as M/s Geneway Bio, China. The firm has submitted that Geneway Bio is Intellect's affiliated entity, however, no documents in support submitted. 3. The comparative characterization data which was previously submitted for RTF bulk in initial dossier is again submitted as of finished product of RTF bulk manufacturer. the firm has submitted following clarification: "Although Intellective Biologics is not marketing Pembrolizumab as finished product, but Intellective Biologics perform stability study, characterization and clinical trials on Drug Product manufactured from RTF. Specifications of (Ready to Fill Bulk) RTF and Drug product are same. In the initial CTD dossier, relevant information pertaining to the Drug Product was incorporated as part

of the RTF Bulk/Drug Product manufactured by M/s Intellective Biologics. Subsequently, in response to the last query, relevant drug product part separately extracted and submitted as a standalone section in Drug Product CTD part. Therefore, the separately submitted information is provided specifically in response to the query and should not be considered as duplicate submission of the previously provided data." 4. Comparative study data of applied product with finished product of ready-to-fill bulk manufacturer is submitted as single table without any supporting data. 6. The clinical trial data provided does not include immunogenicity studies. 8. The firm has submitted data of few tests regarding Primary Structure of finished product performed by Harvard Medical School in comparison with Innovator product. 9. The firm has also submitted Pharmacokinetic and toxicology study report under non-clinical studies in animals performed by Institute of Chemical Sciences, Government College University, Lahore. 10. The batch size of trial batches manufactured by local manufacturer is 130 vials each.

Decision

Deferred

Registration Board discussed the case in detail that data in light of decision of 360th meeting is still not completed by the firm as firm has not submitted the following:

i. CoPP issued by regulatory authority of country of origin for finished product manufactured by ready-to-fill bulk manufacturer.

ii. Batches mentioned in COAs, stability in initial dossier and in subsequent submissions are different.

iii. Comparative study data of applied product with finished product of ready-to-fill bulk manufacturer is submitted as single table without any supporting data.

iv. In clinical trials, immunogenicity studies are not performed.

The Board deliberated that CoPP of finished product manufactured by ready-to-fill bulk manufacturer is not available as the product is not registered in that country due to patent issues. Moreover, Pembrolizumab Injection is indicated in treatment of 17 cancers and is already being imported on patient need basis and the clinical trial data of this product conducted in comparison with Innovator is indicating its safety and efficacy. Hence, keeping in view the above discussion and public health need of Pembrolizumab Injection; Registration Board deferred the case and decided as follows:

In view of the substantial disease burden associated with these malignancies and the established clinical utility of Pembrolizumab in appropriately selected patients, the Board considered that the continued availability of the product may contribute to addressing an important unmet therapeutic need and facilitate patient access to an established treatment option for cancer. Furthermore, in consideration of the approval of the product by ANMAT, Argentina, the application may be processed further in accordance with the applicable regulatory requirements, subject to satisfactory assessment of the submitted quality, safety, efficacy, and Good Manufacturing Practices (GMP)-related evidence.

In view of the above, the Registration Board decided that a product-specific inspection of the overseas manufacturing facility shall be conducted to verify compliance with applicable GMP requirements and to verify the submitted data. The matter regarding the grant of Marketing Authorization (MA) shall be considered subsequently upon satisfactory confirmation of GMP compliance, along with a comprehensive evaluation and verification of the submitted technical and scientific data. The final regulatory decision shall be based on the totality of the available evidence, including the outcome of the product-specific inspection and the adequacy of the submitted quality, non-clinical, and clinical data, as well

	as any other information considered relevant to establishing the overall benefit-risk profile of the product. Product specific inspection, shall be conducted by following panel of experts: i. Two evaluators from Division of Biological Evaluation & Research, DRAP. ii. Dr. Ali Jan, Director Drug TestingLaboratory, Quetta. iii. Mr. Syed Adnan Rizvi, Director Drug Testing Laboratory, Karachi. iv. Mr. Asad Abrar, Director Drug Testing Laboratory, Bahawalpur.	
61	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(E96-ZQ7-N45S, 2026-06-18)
	Detail of Fee Submitted	38700, 2026-02-16,
	The proposed proprietary name / brand name	**DENORIN 2000IU Anti-Xa/0.2ml Injection**
	Label Claim	Each vial contains: Enoxaparin Sodium..... 20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	De-regulated-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 15 to 30°C
	For generic drugs (me-too Status)	Clexane by Sanofi Aventis
	Pharmacotherapeutic Group of (API)	Low Molecular Weight Heparin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Accelerated (40C) for 06 months & Realtime (30C) for 6 months, Three Batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP clearance invoice no. RO-CF96B8 dated 04-09-2024.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Data in light of decision of 289th meeting is submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (40C) for 06 months & Realtime (30C) for 36 months, Three Batches
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	GMP Certificate based on inspection dated 01-07-2024.
	Evidence of approval of manufacturing facility	Section regularization letter dated 14-11-2025.
	Evaluation Remarks	
	.	
	Decision	
	Approved Registration Board approved the product.	
62	Case Category	Routine (M. Zubair Masood)

	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(752-H1B-A4ND, 2026-06-18)
	Detail of Fee Submitted	38700, 2026-02-16,
	The proposed proprietary name / brand name	**DENORIN 8000IU Anti-Xa/0.8ml Injection**
	Label Claim	Each vial (0.8ml) contains: Enoxaparin Sodium..... 80mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	De-regulated-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 15 to 30°C
	For generic drugs (me-too Status)	Clexane by Sanofi Aventis
	Pharmacotherapeutic Group of (API)	Low Molecular Weight Heparin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Accelerated (40C) for 06 months & Realtime (30C) for 6 months, Three Batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP clearance invoice no. RO-CF96B8 dated 04-09-2024.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Data in light of decision of 289th meeting is submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (40C) for 06 months & Realtime (30C) for 36 months, Three Batches
	The status in reference regulatory authorities	USFDA - LOVENOX
	GMP status of the firm	GMP Certificate based on inspection dated 01-07-2024.
	Evidence of approval of manufacturing facility	Section regularization letter dated 14-11-2025.
	Evaluation Remarks	
	.	
	Decision	
	Approved Registration Board approved the product.	
63	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**Agriprom Pakistan (Pvt) Ltd.** 1st Floor, Plot no. 19-B Off Abdul Sattar Eidhi Road near Qazalbash Chowk, Lahore **(05-352-0066-074116D)**
	Application Form Dy. No / Tracking ID & date of submission	(HBB-JPN-2ZMX, 2026-01-15)
	Detail of Fee Submitted	313500, 2026-01-14,
	The proposed proprietary name / brand name	**Yemune Reo 4 Plus**
	Label Claim	Each dose (0.5ml) of vaccine contains: Newcastle Disease virus LaSota strain, inactivated ... ≥ $10^{8.7}EID_{50}$ before inactivation Infectious Bronchitis virus M41 strain, inactivated ... ≥ $10^{6.2}EID_{50}$ before inactivation Infectious Bursal Disease virus, VP2 protein, ...

		AGP titer ≥ 1:16 Avian Viral Arthritis Virus AV2311 strain, ... ≥ $10^{6.7}ELD_{50}$ before inactivation
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	500 ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)2°C to 8°C
	For generic drugs (me-too Status)	IZOVAC ND-IB-IBD-REO
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Yebio Bioengineering Co., Ltd.-No. 260 Heyuan Road, Hongdao, Qingdao-China
	Name, address of Marketing Authorization Holder:	Yebio Bioengineering Co., Ltd. of Qingdao, No. 21 Aodong Nan Road, Hongdao, Qingdao, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille FSC No. (2025)100 dated 23-07-2025. Scanned Apostille FSC No. (2025) GMP 15005 dated 07-05-2025.
	Details of Authorization Letter :	Scanned Apostille Distribution agreement dated 22-01-2025 and supplementary agreement dated 17-06-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	The case was approved in 354th meeting and Virtual Inspection of Manufacturer Abroad Letter No. 12-2/2025-DD(BD) dated 22 April 2026 was also issued. Subsequently, the applicant has submitted a request through the Case Management System (Tracking ID: 1N1-SS4-5LSL) for withdrawal of the registration application, stating that the manufacturer is not willing to undergo the virtual audit. The applicant's request is reproduced below: "These applications were discussed and approved in principle during the 354th Registration Board Meeting held on 04-05 March 2026. Subsequently, we received the Virtual Inspection of Manufacturer Abroad Letter No. 12-2/2025-DD(BD) dated 22 April 2026. However, M/s Yebio Bioengineering Co., Ltd. (China) has not prepared for inspection and reporting in a positive manner In view of the above, it is requested that the registration applications for the aforementioned products may kindly be withdrawn/cancelled from DRAP records. It is further requested that the proposed virtual inspection of the manufacturing facility may also be cancelled accordingly. We would also like to bring a critical matter to your kind notice regarding the non-serious and potentially deceptive track record of M/s Yebio Bioengineering Co., Ltd. (China). It is the second time they did it in Pakistan. Prior to their engagement with us, this same manufacturer entered into an agreement with M/s Gallimune International and terminated the contract when it came time to prepare for the official DRAP inspection. This repetitive behavior indicates that the manufacturer may not be compliant with regulatory standards or is intentionally avoiding a formal inspection by the Pakistani authority. Their non-cooperative actions have resulted in a severe waste of financial resources, time, and investment for Pakistani companies, while also delaying the entry of genuine products into the Pakistani veterinary market. We request that DRAP note this manufacturer's history for future reference to safeguard local entities from further financial exploitation." The case was rejected by the Board in its 360th meeting as withdrawn, however, due to some technical issue, the case was not extracted in final minutes. Hence, it is again placed for decision please.	
	Decision	
	Rejected Registration Board rejected the application as withdrawn by the firm.	
64	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**Agriprom Pakistan (Pvt) Ltd.** 1st Floor, Plot no. 19-B Off Abdul Sattar Eidhi Road near Qazalbash Chowk, Lahore **(05-352-0066-074116D)**

Application Form Dy. No / Tracking ID & date of submission	(1A7-9DM-GZY1, 2026-01-15)
Detail of Fee Submitted	313500, 2026-01-14,
The proposed proprietary name / brand name	**Yevac NBE**
Label Claim	Each dose (0.5ml) of vaccine contains: Newcastle Disease virus LaSota strain, inactivated ... $\geq 10^{8.1}EID_{50}$ before inactivation Infectious Bronchitis virus M41 strain, inactivated ... $\geq 10^{6.6}EID_{50}$ before inactivation Egg Drop Syndrome virus NE4 strain, inactivated ... $\geq 10^{6.6}EID_{50}$ before inactivation
Reference to Finished product specifications	European Pharmacopeia
Proposed Pack Size	500 ml-De-Controlled
Shelf Life (Unit)	24 Year(s)2°C to 8°C
For generic drugs (me-too Status)	Medivac ND EDS IB
Pharmacotherapeutic Group of (API)	Veterinary Vaccine
Name, address of Manufacturing site:	Yebio Bioengineering Co., Ltd.-No. 260 Heyuan Road, Hongdao, Qingdao-China
Name, address of Marketing Authorization Holder:	Yebio Bioengineering Co., Ltd. of Qingdao, No. 21 Aodong Nan Road, Hongdao, Qingdao, China
Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille FSC No. (2025)77 dated 30-06-2025. Scanned Apostille FSC No. (2025) GMP 15005 dated 07-05-2025.
Details of Authorization Letter :	Scanned Apostille Distribution agreement dated 22-01-2025 and supplementary agreement dated 17-06-2025.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A

Evaluation Remarks

The case was approved in 354th meeting and Virtual Inspection of Manufacturer Abroad Letter No. 12-2/2025-DD(BD) dated 22 April 2026 was also issued. Subsequently, the applicant has submitted a request through the Case Management System (Tracking ID: 1N1-SS4-5LSL) for withdrawal of the registration application, stating that the manufacturer is not willing to undergo the virtual audit. The applicant's request is reproduced below: "These applications were discussed and approved in principle during the 354th Registration Board Meeting held on 04-05 March 2026. Subsequently, we received the Virtual Inspection of Manufacturer Abroad Letter No. 12-2/2025-DD(BD) dated 22 April 2026. However, M/s Yebio Bioengineering Co., Ltd. (China) has not prepared for inspection and reporting in a positive manner In view of the above, it is requested that the registration applications for the aforementioned products may kindly be withdrawn/cancelled from DRAP records. It is further requested that the proposed virtual inspection of the manufacturing facility may also be cancelled accordingly. We would also like to bring a critical matter to your kind notice regarding the non-serious and potentially deceptive track record of M/s Yebio Bioengineering Co., Ltd. (China). It is the second time they did it in Pakistan. Prior to their engagement with us, this same manufacturer entered into an agreement with M/s Gallimune International and terminated the contract when it came time to prepare for the official DRAP inspection. This repetitive behavior indicates that the manufacturer may not be compliant with regulatory standards or is intentionally avoiding a formal inspection by the Pakistani authority. Their non-cooperative actions have resulted in a severe waste of financial resources, time, and investment for Pakistani companies, while also delaying the entry of genuine products into the Pakistani veterinary market. We request that DRAP note this manufacturer's history for future reference to safeguard local entities from further financial exploitation." The case was rejected by the Board in its 360th meeting as withdrawn, however, due to some technical issue, the case was not extracted in final minutes. Hence, it is again placed for decision please.

	Decision	
	Rejected Registration Board rejected the application as withdrawn by the firm.	
65	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**Agriprom Pakistan (Pvt) Ltd.** 1st Floor, Plot no. 19-B Off Abdul Sattar Eidhi Road near Qazalbash Chowk, Lahore **(05-352-0066-074116D)**
	Application Form Dy. No / Tracking ID & date of submission	(WXD-52J-VWUB, 2026-01-15)
	Detail of Fee Submitted	313500, 2026-01-14,
	The proposed proprietary name / brand name	**Yemune NBG**
	Label Claim	Each dose (0.5ml) of vaccine contains: Newcastle Disease virus LaSota strain, inactivated.....$\geq 10^{8.1}EID_{50}$ before inactivation Infectious Bronchitis virus M41 strain, inactivated ... $\geq 10^{6.1}EID_{50}$ before inactivation Infectious Bursal Disease virus, VP2 protein ... AGP titer $\geq$ 1:16
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	500 ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)2°C to 8°C
	For generic drugs (me-too Status)	Medivac ND IB IBD
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Yebio Bioengineering Co., Ltd.-No. 260 Heyuan Road, Hongdao, Qingdao-China
	Name, address of Marketing Authorization Holder:	Yebio Bioengineering Co., Ltd. of Qingdao, No. 21 Aodong Nan Road, Hongdao, Qingdao, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille FSC No. (2025)81 dated 30-06-2025. Scanned Apostille FSC No. (2025) GMP 15005 dated 07-05-2025.
	Details of Authorization Letter :	Scanned Apostille Distribution agreement dated 22-01-2025 and supplementary agreement dated 17-06-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	The case was approved in 354th meeting and Virtual Inspection of Manufacturer Abroad Letter No. 12-2/2025-DD(BD) dated 22 April 2026 was also issued. Subsequently, the applicant has submitted a request through the Case Management System (Tracking ID: 1N1-SS4-5LSL) for withdrawal of the registration application, stating that the manufacturer is not willing to undergo the virtual audit. The applicant's request is reproduced below: "These applications were discussed and approved in principle during the 354th Registration Board Meeting held on 04-05 March 2026. Subsequently, we received the Virtual Inspection of Manufacturer Abroad Letter No. 12-2/2025-DD(BD) dated 22 April 2026. However, M/s Yebio Bioengineering Co., Ltd. (China) has not prepared for inspection and reporting in a positive manner In view of the above, it is requested that the registration applications for the aforementioned products may kindly be withdrawn/cancelled from DRAP records. It is further requested that the proposed virtual inspection of the manufacturing facility may also be cancelled accordingly. We would also like to bring a critical matter to your kind notice regarding the non-serious and potentially deceptive track record of M/s Yebio Bioengineering Co.,	

	Ltd. (China). It is the second time they did it in Pakistan. Prior to their engagement with us, this same manufacturer entered into an agreement with M/s Gallimune International and terminated the contract when it came time to prepare for the official DRAP inspection. This repetitive behavior indicates that the manufacturer may not be compliant with regulatory standards or is intentionally avoiding a formal inspection by the Pakistani authority. Their non-cooperative actions have resulted in a severe waste of financial resources, time, and investment for Pakistani companies, while also delaying the entry of genuine products into the Pakistani veterinary market. We request that DRAP note this manufacturer's history for future reference to safeguard local entities from further financial exploitation." The case was rejected by the Board in its 360th meeting as withdrawn, however, due to some technical issue, the case was not extracted in final minutes. Hence, it is again placed for decision please.	
	Decision	
	Rejected Registration Board rejected the application as withdrawn by the firm.	
66	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**Agriprom Pakistan (Pvt) Ltd.** 1st Floor, Plot no. 19-B Off Abdul Sattar Eidhi Road near Qazalbash Chowk, Lahore **(05-352-0066-074116D)**
	Application Form Dy. No / Tracking ID & date of submission	(5SD-LM5-7Q3M, 2026-01-15)
	Detail of Fee Submitted	313500, 2026-01-14,
	The proposed proprietary name / brand name	**Yeflu NGH9**
	Label Claim	Each dose (0.5ml) contains: Newcastle Disease Virus LaSota strain, inactivated.....$\geq 10^{8.2}EID_{50}$ Avian Influenza Virus subtype H9 YBF003 strain, inactivated ... $\geq 10^{7.2}EID_{50}$ Infectious Bursal Disease Virus, VP2 protein.....AGP titer $\geq$ 1:16
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	500 ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)2°C to 8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Yebio Bioengineering Co., Ltd.-No. 260 Heyuan Road, Hongdao, Qingdao-China
	Name, address of Marketing Authorization Holder:	Yebio Bioengineering Co., Ltd. of Qingdao, No. 21 Aodong Nan Road, Hongdao, Qingdao, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille FSC No. (2025)75 dated 30-06-2025. Scanned Apostille FSC No. (2025) GMP 15005 dated 07-05-2025.
	Details of Authorization Letter :	Scanned Apostille Distribution agreement dated 22-01-2025 and supplementary agreement dated 17-06-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	The case was approved in 354th meeting and Virtual Inspection of Manufacturer Abroad Letter No. 12-2/2025-DD(BD) dated 22 April 2026 was also issued. Subsequently, the applicant has submitted a request through the Case Management System (Tracking ID: 1N1-SS4-5LSL) for withdrawal of	

	the registration application, stating that the manufacturer is not willing to undergo the virtual audit. The applicant's request is reproduced below: "These applications were discussed and approved in principle during the 354th Registration Board Meeting held on 04-05 March 2026. Subsequently, we received the Virtual Inspection of Manufacturer Abroad Letter No. 12-2/2025-DD(BD) dated 22 April 2026. However, M/s Yebio Bioengineering Co., Ltd. (China) has not prepared for inspection and reporting in a positive manner In view of the above, it is requested that the registration applications for the aforementioned products may kindly be withdrawn/cancelled from DRAP records. It is further requested that the proposed virtual inspection of the manufacturing facility may also be cancelled accordingly. We would also like to bring a critical matter to your kind notice regarding the non-serious and potentially deceptive track record of M/s Yebio Bioengineering Co., Ltd. (China). It is the second time they did it in Pakistan. Prior to their engagement with us, this same manufacturer entered into an agreement with M/s Gallimune International and terminated the contract when it came time to prepare for the official DRAP inspection. This repetitive behavior indicates that the manufacturer may not be compliant with regulatory standards or is intentionally avoiding a formal inspection by the Pakistani authority. Their non-cooperative actions have resulted in a severe waste of financial resources, time, and investment for Pakistani companies, while also delaying the entry of genuine products into the Pakistani veterinary market. We request that DRAP note this manufacturer's history for future reference to safeguard local entities from further financial exploitation." The case was rejected by the Board in its 360th meeting as withdrawn, however, due to some technical issue, the case was not extracted in final minutes. Hence, it is again placed for decision please.	
	Decision	
	Rejected Registration Board rejected the application as withdrawn by the firm.	
67	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)**
	Application Form Dy. No / Tracking ID & date of submission	(P6W-4RM-1DS9, 2026-08-06)
	Detail of Fee Submitted	97200, 2026-07-07,
	The proposed proprietary name / brand name	**Tirzephage**
	Label Claim	Each single dose pre-filled pen contains: Tirzepatide 10mg in 0.5ml solution
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year2°C-8°C
	For generic drugs (me-too Status)	• Product Name: Tirvox Injection 10mg/0.5ml • (Approved in 354th DRB Meeting) • • Manufacturer: Weather Folds Pharmaceutical • • Reg.No: 131635
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Nextar Pharma (Pvt) Ltd-Plot No. E-58, North Western, Industrial Zone, Port Qasim, Karachi-
	The status in reference regulatory authorities	MOUNJARO (tirzepatide) Injection, for subcutaneous use Initial U.S. Approval: 2022
	Detail of previous approval	Zavi 10mg/0.5ml pre-filled pen, DRB 358 Meeting Minutes
	Evaluation Remarks	
	Decision	
	Approved	

Approved with following conditions:

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

ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT.

iii. 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.

iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022.

vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

68	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)**
	Application Form Dy. No / Tracking ID & date of submission	(7RP-GT7-X2AX, 2026-08-06)
	Detail of Fee Submitted	97200, 2026-07-07,
	The proposed proprietary name / brand name	**Tirzephage**
	Label Claim	Each single dose pre-filled pen contains: Tirzepatide 7.5mg in 0.5ml solution
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year2°C-8°C
	For generic drugs (me-too Status)	• Product Name: Tirzee Injection 7.5mg/0.5ml (Approved in 350th DRB Meeting) • Manufacturer: Getz Pharma, Korangi, Karachi. • Reg.No: 130003
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Nextar Pharma (Pvt) Ltd-Plot No. E-58, North Western, Industrial Zone, Port Qasim, Karachi-
	The status in reference regulatory authorities	MOUNJARO (tirzepatide) Injection, for subcutaneous use Initial U.S. Approval: 2022

	Detail of previous approval	Zavi 7.5mg/0.5ml pre-filled pen, DRB 358 Meeting Minutes
	Evaluation Remarks	
	Decision	
	Approved Approved with following conditions: i. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT. iii. 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. iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022. vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
69	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)**
	Application Form Dy. No / Tracking ID & date of submission	(LG8-MW7-9JP7, 2026-08-06)
	Detail of Fee Submitted	97200, 2026-07-07,
	The proposed proprietary name / brand name	**Tirzephage**
	Label Claim	Each single dose pre-filled pen contains: Tirzepatide 5mg in 0.5ml solution
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year2°C-8°C
	For generic drugs (me-too Status)	• Product Name: Tirzee Injection 5mg/0.5ml (Approved in 350th DRB Meeting) • Manufacturer: Getz Pharma, Korangi, Karachi. • Reg.No: 130002

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Nextar Pharma (Pvt) Ltd-Plot No. E-58, North Western, Industrial Zone, Port Qasim, Karachi-
	The status in reference regulatory authorities	MOUNJARO (tirzepatide) Injection, for subcutaneous use Initial U.S. Approval: 2022
	Detail of previous approval	Zavi 5mg/0.5ml pre-filled pen, DRB 358 Meeting Minutes
	Evaluation Remarks	
	Decision	
	Approved Approved with following conditions: i. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT. iii. 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. iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022. vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
70	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)**
	Application Form Dy. No / Tracking ID & date of submission	(LTB-TXS-ZG6T, 2026-08-06)
	Detail of Fee Submitted	97200, 2026-07-07,
	The proposed proprietary name / brand name	**Tirzephage**
	Label Claim	Each single dose pre-filled pen contains: Tirzepatide 2.5mg in 0.5ml solution
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO

	Shelf Life (Unit)	2 Year2°C-8°C
	For generic drugs (me-too Status)	• Product Name: Tirzee Injection 2.5mg/0.5ml (Approved in 350th DRB Meeting) • Manufacturer: Getz Pharma, Korangi, Karachi. • Reg.No: 130001
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Nextar Pharma (Pvt) Ltd-Plot No. E-58, North Western, Industrial Zone, Port Qasim, Karachi-
	The status in reference regulatory authorities	MOUNJARO (tirzepatide) Injection, for subcutaneous use Initial U.S. Approval: 2022
	Detail of previous approval	Zavi 2.5mg/0.5ml pre-filled pen, DRB 358 Meeting Minutes
	Evaluation Remarks	
	Decision	
	Approved Approved with following conditions: i. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT. iii. 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. iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022. vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
71	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Nextar Pharma (pvt) Ltd** Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi **(000777)**
	Application Form Dy. No / Tracking ID & date of submission	(U3S-U7U-H1ZD, 2026-08-08)
	Detail of Fee Submitted	38700, 2026-07-23,

	The proposed proprietary name / brand name	**Tizaro 10mg/0.5ml injection**
	Label Claim	Each Single dose Pre Filled Pen contains: Tirzepatide 10mg in 0.5ml solution
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1'S PFP-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 2-8ºC
	For generic drugs (me-too Status)	Tirzee Injection 10mg/0.5ml , Getz Pharma, Korangi, Karachi.
	Pharmacotherapeutic Group of (API)	GIP and GLP-1 receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing
	The status in reference regulatory authorities	MOUNJARO® (Tirzepatide) Injection, for subcutaneous use 10mg/0.5 mL ,Lilly USA, LLC, Indianapolis, IN 46285, USA
	Detail of previous approval	
	Evaluation Remarks	
	Registration has been issued in name of M/s The Searle Company Limited manufactured by M/s Nextar Pharma (Pvt.) Ltd as per approval of Registration Board in its 358th meeting.	
	Decision	
	Approved Approved with following conditions i. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT. iii. 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. iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022. vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
72	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Nextar Pharma (pvt) Ltd** Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi **(000777)**

	Application Form Dy. No / Tracking ID & date of submission	(1P2-G43-NH7N, 2026-08-05)
	Detail of Fee Submitted	38700, 2026-07-23,
	The proposed proprietary name / brand name	**Tizaro 7.5mg/0.5ml injection**
	Label Claim	Each Single dose Pre Filled Pen contains: Tirzepatide 7.5mg in 0.5ml solution
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1'S PFP-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 2-8ºC
	For generic drugs (me-too Status)	Tirzee Injection 7.5mg/0.5ml , Getz Pharma, Korangi, Karachi.
	Pharmacotherapeutic Group of (API)	GIP & GLP Agonist
	Name, address of Manufacturing site:	Self Manufacturing
	The status in reference regulatory authorities	MOUNJARO® (Tirzepatide) Injection, for subcutaneous use 7.5mg/0.5 mL ,Lilly USA, LLC, Indianapolis, IN 46285, USA
	Detail of previous approval	
	Evaluation Remarks	
	Decision	

Approved

Approved with following conditions:

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

ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT.

iii. 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.

iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022.

vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

73	Case Category	Routine (Muneeb Ahmed Cheema)

Name, address of Applicant.	**Nextar Pharma (pvt) Ltd** Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi **(000777)**
Application Form Dy. No / Tracking ID & date of submission	(ATY-VPQ-QY6V, 2026-08-08)
Detail of Fee Submitted	38700, 2026-07-23,
The proposed proprietary name / brand name	**Tizaro 15mg/0.5ml injection**
Label Claim	Each single dose pre-filled pen contains: Tirzepatide 15mg in 0.5ml solution
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1'S PFP-As per SRO
Shelf Life (Unit)	2 Year(s)Store between 2-8ºC
For generic drugs (me-too Status)	Tirzee Injection 15mg/0.5ml , Getz Pharma, Korangi, Karachi.
Pharmacotherapeutic Group of (API)	GIP & GLP Agonist
Name, address of Manufacturing site:	Self Manufacturing
The status in reference regulatory authorities	MOUNJARO® (Tirzepatide) Injection, for subcutaneous use 15mg/0.5 mL ,Lilly USA, LLC, Indianapolis, IN 46285, USA
Detail of previous approval	

Evaluation Remarks

Registration letter has already been issued in name of M/s The Searle Company Limited manufactured by M/s Nextar Pharma (Pvt.) Ltd as per approval of Registration Board in its 358th meeting.

Decision

Approved

Approved with following conditions:

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

ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT.

iii. 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.

iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022.

vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

74	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Nextar Pharma (pvt) Ltd** Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi **(000777)**
	Application Form Dy. No / Tracking ID & date of submission	(JBQ-YJD-787A, 2026-08-08)
	Detail of Fee Submitted	38700, 2026-07-23,
	The proposed proprietary name / brand name	**Tizaro 12.5mg/0.5ml injection**
	Label Claim	Each Single dose Pre Filled Pen contains: Tirzepatide 12.5mg in 0.5ml solution
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1'S PFP-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 2-8ºC
	For generic drugs (me-too Status)	Tirzee Injection 12.5mg/0.5ml , Getz Pharma, Korangi, Karachi.
	Pharmacotherapeutic Group of (API)	GIP & GLP Agonist
	Name, address of Manufacturing site:	Self Manufacturing
	The status in reference regulatory authorities	MOUNJARO® (Tirzepatide) Injection, for subcutaneous use 12.5mg/0.5 mL ,Lilly USA, LLC, Indianapolis, IN 46285, USA
	Detail of previous approval	
	Evaluation Remarks	
	Registration has been issued in name of M/s The Searle Company Limited manufactured by M/s Nextar Pharma (Pvt.) Ltd as per approval of Registration Board in its 358th meeting.	
	Decision	

Approved

Approved with following conditions:

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

ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT.

iii. 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.

iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022.

vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

75	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Nextar Pharma (pvt) Ltd** Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi **(000777)**
	Application Form Dy. No / Tracking ID & date of submission	(PH1-ALM-5PEV, 2026-08-08)
	Detail of Fee Submitted	38700, 2026-07-23,
	The proposed proprietary name / brand name	**Tizaro 5mg/0.5ml injection**
	Label Claim	Each pre-filled pen contains 5 mg of tirzepatide in 0.5 ml solution.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1'S PFP-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 2-8ºC
	For generic drugs (me-too Status)	Tirzee Injection 5mg/0.5ml , Getz Pharma, Korangi, Karachi.
	Pharmacotherapeutic Group of (API)	GIP & GLP Agonist
	Name, address of Manufacturing site:	Self Manufacturing
	The status in reference regulatory authorities	MOUNJARO® (Tirzepatide) Injection, for subcutaneous use 5 mg/0.5 mL ,Lilly USA, LLC, Indianapolis, IN 46285, USA
	Detail of previous approval	
	Evaluation Remarks	
	Registration has been issued in name of M/s The Searle Company Limited manufactured by M/s Nextar Pharma (Pvt.) Ltd as per approval of Registration Board in its 358th meeting.	
	Decision	

Approved

Approved with following conditions:

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

ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT.

iii. 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.

iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022.

vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

76	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Nextar Pharma (pvt) Ltd** Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi **(000777)**
	Application Form Dy. No / Tracking ID & date of submission	(SJA-VTA-G9UR, 2026-08-08)
	Detail of Fee Submitted	38700, 2026-07-23,
	The proposed proprietary name / brand name	**Tizaro 2.5mg/0.5ml injection**
	Label Claim	Each Single dose Pre Filled Pen contains: Tirzepatide 2.5mg in 0.5ml Solution
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1'S PFP-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 2-8ºC
	For generic drugs (me-too Status)	Tirzee Injection 2.5mg/0.5ml , Getz Pharma, Korangi, Karachi.
	Pharmacotherapeutic Group of (API)	GIP & GLP Agonist
	Name, address of Manufacturing site:	Self Manufacturing
	The status in reference regulatory authorities	MOUNJARO® (Tirzepatide) Injection, for subcutaneous use2.5 mg/0.5 mL ,Lilly USA, LLC, Indianapolis, IN 46285, USA
	Detail of previous approval	

Evaluation Remarks

Registration has been issued in name of M/s The Searle Company Limited manufactured by M/s Nextar Pharma (Pvt.) Ltd as per approval of Registration Board in its 358th meeting.

Decision

Approved

Approved with following conditions

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

and same shall immediately be reported to the Division of BE&R and QA&LT.

iii. 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.

iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022.

vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

77

Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**
Application Form Dy. No / Tracking ID & date of submission	(P5M-TBN-XWWV, 2026-08-08)
Detail of Fee Submitted	97200, 2026-07-14,
The proposed proprietary name / brand name	**Glyzep 7.5mg/0.5ml Injection**
Label Claim	Each Pre-filled single-dose pen (0.5ml) 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)2°C to 8°C
For generic drugs (me-too Status)	Tirzee Injection 7.5mg/0.5ml by Getz Pharma (Pvt.) Limited
Pharmacotherapeutic Group of (API)	GIP & GLP Agonist
Name, address of Manufacturing site:	Nextar Pharma (Pvt.) Ltd-Plot No. E-58 North Western Industrial Zone, Port Qasim Karachi - Pakistan-
The status in reference regulatory authorities	USFDA Approved [MOUNJARO (tirzepatide) Injection, for subcutaneous use is registered and being marketed by Lilly USA, LLC USA]
Detail of previous approval	Zavi 7.5mg/0.5ml PFS with Disposable Auto-injector (Xavy" as per Registration Certificate). Meeting No. 358

Evaluation Remarks

Registration has been issued in name of M/s The Searle Company Limited manufactured by M/s Nextar Pharma (Pvt.) Ltd as per approval of Registration Board in its 358th meeting.

Decision

Approved

Approved with following conditions:

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

ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT.

iii. 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.

iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022.

vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

78		
	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(8P4-WYJ-8VNL, 2026-08-08)
	Detail of Fee Submitted	97200, 2026-07-14,
	The proposed proprietary name / brand name	**Glyzep 15mg/0.5ml Injection**
	Label Claim	Each Pre-filled single-dose pen (0.5ml) contains: Tirzepatide.....15mg (Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)2°C to 8°C
	For generic drugs (me-too Status)	Zeptide 15mg/0.5ml by BF Biosciences Ltd.
	Pharmacotherapeutic Group of (API)	GIP & GLP Agonist
	Name, address of Manufacturing site:	Nextar Pharma (Pvt.) Ltd-Plot No. E-58 North Western Industrial Zone, Port Qasim Karachi - Pakistan.-
	The status in reference regulatory authorities	USFDA Approved [MOUNJARO (tirzepatide) Injection, for subcutaneous use is registered and being marketed by Lilly USA, LLC US
	Detail of previous approval	Zavi 15mg/0.5ml PFS with Disposable Auto-injector (Xavy" as per Registration Certificate). Meeting No. 358
	Evaluation Remarks	
	Registration has been issued in name of M/s The Searle Company Limited manufactured by M/s Nextar Pharma (Pvt.) Ltd as per approval of Registration Board in its 358th meeting.	
	Decision	

Approved

Approved with following conditions:

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

ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT.

iii. 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.

iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022.

vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

79

Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**
Application Form Dy. No / Tracking ID & date of submission	(RDU-6U4-EDGP, 2026-08-08)
Detail of Fee Submitted	97200, 2026-07-14,
The proposed proprietary name / brand name	**Glyzep 12.5mg/0.5ml PFS with disposable Auto-injector**
Label Claim	Each Pre-filled single-dose pen (0.5ml) contains: Tirzepatide.....12.5mg (Innovaator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-De-Controlled
Shelf Life (Unit)	2 Year(s)2°C to 8°C
For generic drugs (me-too Status)	Tirzee Injection 12.5mg/0.5ml by Getz Pharma (Pvt.) Limited
Pharmacotherapeutic Group of (API)	GIP & GLP Agonist
Name, address of Manufacturing site:	Nextar Pharma (Pvt.) Ltd-Plot No. E-58 North Western Industrial Zone, Port Qasim Karachi - Pakistan.-

	The status in reference regulatory authorities	USFDA Approved [MOUNJARO (tirzepatide) Injection, for subcutaneous use is registered and being marketed by Lilly USA, LLC US
	Detail of previous approval	Zavi 12.5mgmg/0.5ml PFS with Disposable Auto-injector (Xavy" as per Registration Certificate). Meeting No. 358
	Evaluation Remarks	
	Registration has been issued in name of M/s The Searle Company Limited manufactured by M/s Nextar Pharma (Pvt.) Ltd as per approval of Registration Board in its 358th meeting.	
	Decision	
	Approved Approved with following conditions: i. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT. iii. 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. iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022. vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
80	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(9TA-RTU-41MS, 2026-08-08)
	Detail of Fee Submitted	97200, 2026-07-14,
	The proposed proprietary name / brand name	**Glyzep 5mg/0.5ml Injection**
	Label Claim	Each Pre-filled single-dose pen (0.5ml) contains: Tirzepatide.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled

	Shelf Life (Unit)	2 Year(s)2°C to 8°C
	For generic drugs (me-too Status)	Tirzee Injection 5mg/0.5ml by Getz Pharma (Pvt.) Limited
	Pharmacotherapeutic Group of (API)	GIP & GLP Agonist
	Name, address of Manufacturing site:	Nextar Pharma (Pvt.) Ltd-Plot No. E-58 North Western Industrial Zone, Port Qasim Karachi - Pakistan.-
	The status in reference regulatory authorities	USFDA Approved [MOUNJARO (tirzepatide) Injection, for subcutaneous use is registered and being marketed by Lilly USA, LLC USA]
	Detail of previous approval	Zavi 5mg/0.5ml PFS with Disposable Auto-injector (Xavy" as per Registration Certificate). Meeting No. 358
	Evaluation Remarks	
	Registration has been issued in name of M/s The Searle Company Limited manufactured by M/s Nextar Pharma (Pvt.) Ltd as per approval of Registration Board in its 358th meeting.	
	Decision	
	Approved Approved with following conditions: i. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT. iii. 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. iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022. vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
81	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**

Application Form Dy. No / Tracking ID & date of submission	(NML-TNS-AMH8, 2026-08-08)
Detail of Fee Submitted	97200, 2026-07-14,
The proposed proprietary name / brand name	**Glyzep 10mg/0.5ml Injection**
Label Claim	Each Pre-filled single-dose pen (0.5ml) contains: Tirzepatide.....10mg (Innovator's Specs.)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-De-Controlled
Shelf Life (Unit)	2 Year(s)2°C to 8°C
For generic drugs (me-too Status)	Tirzee Injection 10mg/0.5ml by Getz Pharma (Pvt.) Limited
Pharmacotherapeutic Group of (API)	GIP & GLP Agonist
Name, address of Manufacturing site:	Nextar Pharma (Pvt.) Ltd-Plot No. E-58 North Western Industrial Zone, Port Qasim Karachi - Pakistan.-
The status in reference regulatory authorities	USFDA Approved [MOUNJARO (tirzepatide) Injection, for subcutaneous use is registered and being marketed by Lilly USA, LLC US
Detail of previous approval	Zavi 10mg/0.5ml PFS with Disposable Auto-injector (Xavy" as per Registration Certificate). Meeting No. 358

Evaluation Remarks

Registration has been issued in name of M/s The Searle Company Limited manufactured by M/s Nextar Pharma (Pvt.) Ltd as per approval of Registration Board in its 358th meeting.

Decision

Approved

Approved with following conditions:

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

ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT.

iii. 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.

iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022.

vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

82	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(JJP-A1W-L8LD, 2026-08-08)
	Detail of Fee Submitted	97200, 2026-07-14,
	The proposed proprietary name / brand name	**Glyzep 2.5mg/0.5ml Injection**
	Label Claim	Each Pre-filled single-dose pen (0.5ml) 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)2°C to 8°C
	For generic drugs (me-too Status)	Tirzee Injection 2.5mg/0.5ml by Getz Pharma (Pvt.) Limited
	Pharmacotherapeutic Group of (API)	GIP & GLP Agonist
	Name, address of Manufacturing site:	Nextar Pharma (Pvt.) Ltd-Plot No. E-58 North Western Industrial Zone, Port Qasim Karachi - Pakistan.-
	The status in reference regulatory authorities	USFDA Approved [MOUNJARO (tirzepatide) Injection, for subcutaneous use is registered and being marketed by Lilly USA, LLC USA]
	Detail of previous approval	Zavi 2.5mg/0.5ml PFS with Disposable Auto-injector (Xavy" as per Registration Certificate). Meeting No. 358
	Evaluation Remarks	
	Registration has been issued in name of M/s The Searle Company Limited manufactured by M/s Nextar Pharma (Pvt.) Ltd as per approval of Registration Board in its 358th meeting.	
	Decision	
	Approved Approved with following conditions: i. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT. iii. 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.

iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022.

vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

83	Case Category	Priority As Per 257-M of RB (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	(X1X-Q38-8NXJ, 2026-08-06)
	Detail of Fee Submitted	313500, 2026-07-16,
	The proposed proprietary name / brand name	**PROVARIX**
	Label Claim	One dose (approximately 0.5 mL) of reconstituted vaccine contains: Live, attenuated varicella-zoster virus, Oka strain*.....≥3.3 lg PFU
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store at 2-8°C, Donot feeze.
	For generic drugs (me-too Status)	Varilrix Vaccine, Reg. No. 028421,GSK
	Pharmacotherapeutic Group of (API)	Varicella Vaccine
	Name, address of Manufacturing site:	Sinovac (Dalian) Vaccine Technology-No. 36, 2nd Life Road, DD Port, Economic and Technological Development Zone, Dalian-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	Sinovac (Dalian) Vaccine Technology, No. 36, 2nd Life Road, DD Port, Economic and Technological Development Zone, Dalian, China
	Details of Certificates (CoPP/FSC/cGMP):	WHO PQ Vaccine
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	VARIVAX, USFDA Approved Merck Sharp & Dohme LLC
	Evaluation Remarks	
	The applied product is WHO prequalified and can be verified at Varicella Vaccine, Live | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)	
	Decision	
	Approved Keeping in view the WHO PQ status, Registration Board approved the product as per Import Policy for Finished Drugs.	

84	Case Category	Routine (Muneeb Ahmed Cheema)
	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	(8B8-RES-HNV7, 2026-07-09)
	Detail of Fee Submitted	313500, 2026-06-11,
	The proposed proprietary name / brand name	**REVIORA**
	Label Claim	One vial of 4 mL of concentrate contains 100 mg of pembrolizumab. Each mL of concentrate contains 25 mg of pembrolizumab.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 Glass Vial-Controlled
	Shelf Life (Unit)	36 Month(s)Store in a refrigerator (2 °C – 8 °C). Do not freeze. Store in the original carton in order to protect from light.
	For generic drugs (me-too Status)	Pembro Injection (Pembrolizumab 25mg/ml), MAH in Pakistan: Pharmevo (Pvt.) Ltd., Approved in 353rd Drug Registration Board meeting held on 14-15 January 2026
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, PD -1/PD L-1 (Programmed cell death protein 1/death ligand 1) inhibitors. ATC code: L01FF02
	Name, address of Manufacturing site:	Sinergium Biotech S.A.-Route 9, KM 38.7, Garín, Escobar District, Province of Buenos Aires, Argentine Republic.-Argentina
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	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):	GMP Certificate issued by ANMAT is attached
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The primary long-term stability study is being conducted at ≤ −55°C ± 10°C, with a planned duration of 36 months. However, only 3 months of long-term stability data were available for all three primary GMP/F45 DS batches at the time of the dossier. In addition, accelerated stability data are available for up to 3 months at 5°C ± 3°C
	The status in reference regulatory authorities	Reference Biological is US-FDA, EMA-EUROPE, MHRA-UK Approved
	Evaluation Remarks	
	General Information: The applicant developed two formulations of pembrolizumab MB12 during the product development program. F0 was the initial formulation designed to mimic the reference medicinal product (Keytruda), comprising L-histidine, L-histidine HCl, sucrose and polysorbate 80, and was used during early development, including pilot-scale manufacturing and the initial clinical study. Subsequently, the applicant developed F45, a novel formulation containing L-histidine acetate, trehalose, L-arginine/L-arginine HCl and poloxamer, with the stated objectives of ensuring product stability and circumventing patents applicable to the reference product. F45 was subsequently implemented for the intended commercial manufacturing of MB12. Both formulations have the same pharmaceutical form and strength, i.e. 25 mg/mL pembrolizumab concentrate for	

solution for infusion. Analytical/Quality: The applicant has provided comparative physicochemical and functional characterization of MB12 against Keytruda. The F0 formulation was extensively characterized and directly compared with the RMP, while the commercial F45 formulation was also subjected to analytical similarity assessment using commercial-scale batches, demonstrating comparable structural, physicochemical and functional attributes. Non-Clinical: As per submitted dossier, no formulation-specific nonclinical toxicology studies were conducted for either F0 or F45. The applicant relied primarily on the comparative physicochemical and in-vitro functional characterization of MB12 versus Keytruda. Clinical: F0 – Study MB12-C-01-22: The applicant states that this study was conducted using the F0 formulation and was designed to compare MB12 with Keytruda for PK, efficacy, safety and immunogenicity in patients with stage IV NSCLC. However, due to administrative reasons, the study was prematurely terminated and did not achieve the planned sample size. Consequently, the applicant considers the results supportive for PK comparability and the overall similarity exercise, with the conclusions interpreted cautiously because of the limited evaluable population and reduced data scope. For the F0 formulation, study MB12-C-01-22 planned to enroll 174 participants (87 per treatment group) to provide adequate power for the primary PK endpoint. However, the study was prematurely terminated for administrative reasons. Ultimately, 62 participants were enrolled and randomized (30 to MB12 F0 and 32 to Keytruda), of whom 61 actually received treatment. The applicant consequently considers the F0 study supportive rather than pivotal, and states that its conclusions should be interpreted cautiously because of the limited sample size and reduced data scope. F45 – Study MB12-C-02-24 (BENITO): The applicant states that this study uses the commercial F45 formulation and is intended to provide the pivotal clinical evidence for PK and the overall MB12 biosimilarity assessment. It is a repeated-dose comparative PK, safety and immunogenicity study in patients with advanced/non-squamous NSCLC. At the time of the dossier, the study was ongoing/recruiting, and the applicant stated that the results would be submitted to the Agency once available. As of the latest ClinicalTrials.gov update, the study is recruiting, with an estimated 726 participants and no results posted yet. Study Details | NCT06687369 | A Study to Compare Pharmacokinetics, Efficacy, Safety, and Immunogenicity of MB12 (Proposed Pembrolizumab Biosimilar) to Keytruda® in Non-small Cell Lung Cancer (BENITO Study) | ClinicalTrials.gov

Decision

Deferred

The Registration Board noted that there is a significant therapeutic need for Pembrolizumab, a programmed death receptor-1 (PD-1) inhibitor with an established clinical role in the management of a broad range of malignancies. Its clinical applications include, inter alia, melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, urothelial carcinoma, renal cell carcinoma, colorectal cancer with specific molecular characteristics, gastric and gastroesophageal cancers, cervical cancer, endometrial cancer, and other selected malignancies. The availability of Pembrolizumab is therefore considered to be of considerable clinical importance.

In view of the substantial disease burden associated with these malignancies and the established clinical utility of Pembrolizumab in appropriately selected patients, the Board considered that the continued availability of the product may contribute to addressing an important unmet therapeutic need and facilitate patient access to an established treatment option for cancer. Furthermore, in consideration of the approval of the product by ANMAT, Argentina, the application may be processed further in accordance with the applicable regulatory requirements, subject to satisfactory assessment of the submitted quality, safety, efficacy, and Good Manufacturing Practices (GMP)-related evidence.

In view of the above, the Registration Board decided that a product-specific inspection of the overseas manufacturing facility shall be conducted to verify compliance with applicable GMP requirements and to verify the submitted data. The matter regarding the grant of Marketing Authorization (MA) shall be considered subsequently upon satisfactory confirmation of GMP compliance, along with a comprehensive evaluation and verification of the submitted technical and scientific data. The final regulatory decision shall be based on the totality of the available evidence, including the outcome of the product-specific

	inspection and the adequacy of the submitted quality, non-clinical, and clinical data, as well as any other information considered relevant to establishing the overall benefit-risk profile of the product. Product specific inspection shall be conducted by following panel of experts: i. Two evaluators from Division of Biological Evaluation & Research, DRAP. ii. Dr. Ali Jan, Director Drug Testing Laboratory, Quetta. iii. Mr. Syed Adnan Rizvi, Director Drug Testing Laboratory, Karachi. iv. Mr. Asad Abrar, Director Drug Testing Laboratory, Bahawalpur.	
85	Case Category	Import (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**REVIVE HEALTH CARE** 503, 5TH FLOOR EDEN HEIGHTS 6 MAIN GULBERG JAIL ROAD **(05-352-0065-031159D)**
	Application Form Dy. No / Tracking ID & date of submission	(X1B-Y4W-4VTV, 2026-07-08)
	Detail of Fee Submitted	313500, 2026-06-16,
	The proposed proprietary name / brand name	**EYCEPTA Injection 40mg/mL**
	Label Claim	1 mL solution for injection contains 40 mg aflibercept. One vial contains an extractable volume of at least 0.1 mL, equivalent to at least 4 mg aflibercept. This provides a usable amount to deliver a single dose of 0.05 mL containing 2 mg aflibercept.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's vial per carton. Each vial (neutral borosilicate glass tubular injection vial) contains 0.1 mL of solution for withdrawal, and is supplied with 1 - As per SRO
	Shelf Life (Unit)	36 Month(s)Store at 2-8 degree centigrade
	For generic drugs (me-too Status)	EYLEA Injection 40mg/mL, Registration No. 077550
	Pharmacotherapeutic Group of (API)	Ophthalmologicals / Antineovascularisation agents ATC code: S01LA05
	Name, address of Manufacturing site:	Qilu Pharmaceutical Co., Ltd.-8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	Qilu Pharmaceutical Co., Ltd., No.317, Xinluo Road, High-tech Zone, Jinan, Shandong 250101, China, China
	Details of Certificates (CoPP/FSC/cGMP):	The CoPP vide No. ShandonR20261160 indicates GMP Compliance
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies were completed on four PPQ batches . At −20°C ± 5°C, 24-month long-term data showed no significant changes and all tested parameters remained within specifications. Accelerated storage at 5°C ± 3°C for 6 months showed all parameters remained compliant. Freeze-thaw studies also showed no significant

		changes. The proposed storage is −20°C or below for up to 24 months; if stored at 2–8°C, it should be used/filled within 15 days.
	The status in reference regulatory authorities	EYLEA Solution for Intravitreal Injection by Bayer, MHRA Approved
	Evaluation Remarks	
	The submitted quality data demonstrates a high degree of similarity between Aflibercept (QL1207) and the reference medicinal product (Eylea) in terms of primary structure, higher-order structure, physicochemical properties, glycosylation, purity, potency and functional activity. The manufacturing process appears adequately developed, scaled up and validated, with appropriate controls for the drug substance and drug product. The dossier reports 36-month long-term stability data for four PPQ drug-product batches and 6-month accelerated data, together with extensive comparative stability studies against the RMP. The nonclinical package supports comparable pharmacological activity, PK and safety of QL1207 relative to Eylea, without identification of new or unexpected toxicological concerns. The submitted clinical program demonstrates that QL1207 has comparable PK/PD, efficacy, safety and immunogenicity to Eylea. The pivotal Phase III study successfully demonstrated therapeutic similarity in wAMD, while the Phase I study provided supportive safety and PK/PD data in DME.	
	Decision	
	Approved Keeping in view the CoPP indicating the availability of product in country of origin, Registration Board approved the product as per Import Policy for Finished Drugs.	
86	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Atco Laboratories Limited** B-18 SITE KARACHI **(000188)**
	Application Form Dy. No / Tracking ID & date of submission	(WVT-7ZS-ES34, 2026-08-17)
	Detail of Fee Submitted	97200, 2026-07-06,
	The proposed proprietary name / brand name	**SEMPIC SOLUTION FOR INJECTION**
	Label Claim	Each 0.75 ml contains: Semaglutide 1 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-Controlled,2's-Controlled,4's-Controlled
	Shelf Life (Unit)	2 YearStore and transport between 2-8 degree centigrade and avoid freezing.
	For generic drugs (me-too Status)	SEMAVI-PFS 1 mg/ 0.75ml manufactured by M/s Nextar Pharma (Pvt) Ltd,
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. Nextar Pharma (Pvt) Ltd-Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.-
	The status in reference regulatory authorities	Ozempic 1 mg solution for injection in pre-filled pen manufactured by Novo Nordisk A/S
	Detail of previous approval	SEMAVI-PFS 1 mg/ 0.75ml approved in DRB 350 held on 29th July 2025 – 30th July 2025.
	Evaluation Remarks	
	Decision	
	Approved Approved with following conditions	

i. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT.

iii. 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.
iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022.

vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

87		
	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Atco Laboratories Limited** B-18 SITE KARACHI **(000188)**
	Application Form Dy. No / Tracking ID & date of submission	(1G6-PVB-VHDV, 2026-08-17)
	Detail of Fee Submitted	97200, 2026-07-06,
	The proposed proprietary name / brand name	**SEMPIC SOLUTION FOR INJECTION**
	Label Claim	Each 0.375 ml contains: Semaglutide 0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-Controlled,2's-Controlled,4's-Controlled
	Shelf Life (Unit)	2 YearStore and transport between 2-8 degree centigrade and avoid freezing.
	For generic drugs (me-too Status)	SEMAVI-PFS 0.5 mg/ 0.375ml manufactured by M/s Nextar Pharma (Pvt) Ltd,
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. Nextar Pharma (Pvt) Ltd-Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.-
	The status in reference regulatory authorities	Ozempic 0.5 mg solution for injection in pre-filled pen manufactured by Novo Nordisk A/S
	Detail of previous approval	SEMAVI-PFS 0.5 mg/ 0.375ml approved in DRB 350 held on 29th July 2025 – 30th July 2025.
	Evaluation Remarks	
	Decision	

Approved

Approved with following conditions:

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

ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT.

iii. 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.

iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022.

vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

88	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Atco Laboratories Limited** B-18 SITE KARACHI **(000188)**
	Application Form Dy. No / Tracking ID & date of submission	(HAM-NW4-J4BE, 2026-08-17)
	Detail of Fee Submitted	97200, 2026-07-06,
	The proposed proprietary name / brand name	**SEMPIC SOLUTION FOR INJECTION**
	Label Claim	Each 0.188ml contains: Semaglutide 0.25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-Controlled,2's-Controlled,4's-Controlled
	Shelf Life (Unit)	2 YearDo not store and transport above 30 degree centigrade.
	For generic drugs (me-too Status)	SEMAVI-PFS 0.25 mg/ 0. 188ml manufactured by M/s Nextar Pharma (Pvt) Ltd,
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. Nextar Pharma (Pvt) Ltd-Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.-
	The status in reference regulatory authorities	Ozempic 0.25 mg solution for injection in pre-filled pen manufactured by Novo Nordisk A/S

	Detail of previous approval	SEMAVI-PFS 0.25 mg/ 0. 188ml approved in DRB 350 held on 29th July 2025 – 30th July 2025.
	Evaluation Remarks	
	Decision	
	Approved Approved with following conditions: i. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. ii. 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 and same shall immediately be reported to the Division of BE&R and QA&LT. iii. 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. iv. The manufacturer shall perform post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. v. The manufacturer shall actively collect, assess, and report ADRs as per the timelines defined in Rule 11(5) of the Pharmacovigilance Rules 2022. vi. The manufacturer shall submit PBRERs (Periodic Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
89	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Novo Nordisk Pharma (Pvt.) Ltd.** 113, Shahrah-e-Iran, Clifton **(636)**
	Application Form Dy. No / Tracking ID & date of submission	(7Q8-ADH-3WTB, 2026-07-03)
	Detail of Fee Submitted	313500, 2026-06-23,
	The proposed proprietary name / brand name	**Wegovy® 1.5 mg tablets**
	Label Claim	Each tablet contains 1.5 mg semaglutide*. *human glucagon-like peptide-1 (GLP-1) analogue produced in Saccharomyces cerevisiae cells by recombinant DNA technology.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	Alu/Alu blisters of 10 tablets. Pack sizes of: 10, 30 and 90 tablets.-As per SRO
	Shelf Life (Unit)	3 Year(s)Store in the original package in order to protect from moisture and light. This medicinal

		product does not require any special temperature storage conditions
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	GLP Analogue
	Name, address of Manufacturing site:	Batch Release - Novo Nordisk A/S-Novo Allé 1, DK-2880 Bagsværd-Denmark ,Bulk Manufacturer, Primary Packaging and Secondary Packaging - Novo Nordisk A/S-Novo Nordisk Park 1, DK-2760 Måløv-Denmark
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	Novo Nordisk A/S, Novo Alle 1, DK-2880 Bagsvaerd, Denmark
	Details of Certificates (CoPP/FSC/cGMP):	Eudra GMP available
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The drug substance stability programme includes primary, PPQ and process-validation batches. Long-term stability is conducted at −20°C ± 5°C, with studies designed to support a 36-month shelf life, and continued up to 60 months. Accelerated/intermediate studies are conducted at 5°C ± 3°C for 12 months.
	The status in reference regulatory authorities	Approved in USFDA
	Evaluation Remarks	
	Decision	
	Approved Approved subject to submission of valid legalized CoPP issued by regulatory authority of country of origin.	
90	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Novo Nordisk Pharma (Pvt.) Ltd.** 113, Shahrah-e-Iran, Clifton **(636)**
	Application Form Dy. No / Tracking ID & date of submission	(BSQ-5UD-Y6X6, 2026-07-03)
	Detail of Fee Submitted	313500, 2026-06-23,
	The proposed proprietary name / brand name	**Wegovy® 4mg tablets**
	Label Claim	Each tablet contains 4 mg semaglutide*. *human glucagon-like peptide-1 (GLP-1) analogue produced in Saccharomyces cerevisiae cells by recombinant DNA technology.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	Alu/Alu blisters of 10 tablets. Pack sizes of: 10, 30 and 90 tablets.-As per SRO
	Shelf Life (Unit)	3 Year(s)Store in the original package in order to protect from moisture and light. This medicinal product does not require any special temperature storage conditions
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	GLP Analogue
	Name, address of Manufacturing site:	Batch Release - Novo Nordisk A/S-Novo Allé 1, DK-2880 Bagsværd-Denmark ,Bulk Manufacturer, Primary Packaging and

		Secondary Packaging - Novo Nordisk A/S-Novo Nordisk Park 1, DK-2760 Måløv-Denmark
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	Novo Nordisk A/S, Novo Alle 1, DK-2880 Bagsvaerd, Denmark
	Details of Certificates (CoPP/FSC/cGMP):	EU GMP Facility
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The drug substance stability programme includes primary, PPQ and process-validation batches. Long-term stability is conducted at −20°C ± 5°C, with studies designed to support a 36-month shelf life, and continued up to 60 months. Accelerated/intermediate studies are conducted at 5°C ± 3°C for 12 months.
	The status in reference regulatory authorities	Approved in USFDA
	Evaluation Remarks	
	Decision	
	Approved Approved subject to submission of valid legalized CoPP issued by regulatory authority of country of origin.	
91	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Novo Nordisk Pharma (Pvt.) Ltd.** 113, Shahrah-e-Iran, Clifton **(636)**
	Application Form Dy. No / Tracking ID & date of submission	(97N-3VP-R96X, 2026-08-18)
	Detail of Fee Submitted	313500, 2026-06-23,
	The proposed proprietary name / brand name	**Wegovy® 25mg tablets**
	Label Claim	Wegovy 25 mg tablets Each tablet contains 25 mg semaglutide*. *human glucagon-like peptide-1 (GLP-1) analogue produced in Saccharomyces cerevisiae cells by recombinant DNA technology.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	Alu/Alu blisters of 10 tablets. Pack sizes of: 10, 30 and 90 tablets.-As per SRO
	Shelf Life (Unit)	3 Year(s)Store in the original package in order to protect from moisture and light. This medicinal product does not require any special temperature storage conditions
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	GLP Analogue
	Name, address of Manufacturing site:	Batch Release Novo Nordisk A/S-Novo Allé 1, DK-2880 Bagsværd-Denmark ,Bulk Manufacturer, Novo Nordisk Pharmaceutical Industries LP 5235-International Drive Durham, North Carolina 27712-United States of America ,Primary Packaging and Secondary Packaging Novo Nordisk A/S-Hallas Allé 1, DK-4400 Kalundborg-Denmark

	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	Novo Nordisk A/S, Novo Alle 1, DK-2880 Bagsvaerd, Denmark
	Details of Certificates (CoPP/FSC/cGMP):	EU GMP
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The drug substance stability programme includes primary, PPQ and process-validation batches. Long-term stability is conducted at −20°C ± 5°C, with studies designed to support a 36-month shelf life, and continued up to 60 months. Accelerated/intermediate studies are conducted at 5°C ± 3°C for 12 months.
	The status in reference regulatory authorities	Approved in USFDA
	Evaluation Remarks	
	Decision	
	Approved Approved subject to submission of valid legalized CoPP issued by regulatory authority of country of origin.	
92	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Novo Nordisk Pharma (Pvt.) Ltd.** 113, Shahrah-e-Iran, Clifton **(636)**
	Application Form Dy. No / Tracking ID & date of submission	(RG4-NN3-UBEN, 2026-08-18)
	Detail of Fee Submitted	313500, 2026-06-23,
	The proposed proprietary name / brand name	**Wegovy® 9mg tablets**
	Label Claim	Wegovy 9 mg tablets Each tablet contains 9 mg semaglutide*. *human glucagon-like peptide-1 (GLP-1) analogue produced in Saccharomyces cerevisiae cells by recombinant DNA technology.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	Alu/Alu blisters of 10 tablets. Pack sizes of: 10, 30 and 90 tablets.-As per SRO
	Shelf Life (Unit)	3 Year(s)Store in the original package in order to protect from moisture and light. This medicinal product does not require any special temperature storage conditions
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	GLP Analogue
	Name, address of Manufacturing site:	Batch Release - Novo Nordisk A/S-Novo Allé 1, DK-2880 Bagsværd-Denmark ,Bulk Manufacturer, Primary Packaging and Secondary Packaging - Novo Nordisk A/S-Novo Nordisk Park 1, DK-2760 Måløv-Denmark
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	Novo Nordisk A/S, Novo Alle 1, DK-2880 Bagsvaerd, Denmark
	Details of Certificates (CoPP/FSC/cGMP):	EU GMP
	Details of Authorization Letter :	NA

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The drug substance stability programme includes primary, PPQ and process-validation batches. Long-term stability is conducted at −20°C ± 5°C, with studies designed to support a 36-month shelf life, and continued up to 60 months. Accelerated/intermediate studies are conducted at 5°C ± 3°C for 12 months.
	The status in reference regulatory authorities	Approved in USFDA
	Evaluation Remarks	
	Approved subject to submission of valid legalized CoPP issued by regulatory authority of country of origin.	
	Decision	
	Approved	
93	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Amson Vaccines & Pharma (Pvt.) Ltd** Plot # 115, Industrial Triangle Kahuta Road **(017/DSL(D)/PS&DC-ICT/2025)**
	Application Form Dy. No / Tracking ID & date of submission	(2HL-7BW-GB75, 2026-08-16)
	Detail of Fee Submitted	313500, 2026-03-25,
	The proposed proprietary name / brand name	**BIO-TCV Injection 2.5ml (05 Doses)**
	Label Claim	Each 0.5ml dose contains: Typhoid vi polysaccharide conjugated to Diphtheria Toxoid .....25 mcg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	Box, 1 vial @ 05 doses (2.5 mL) -As per SRO,Box, 10 vials @ 05 doses (2.5 mL) -As per SRO
	Shelf Life (Unit)	2 Year(s)+2 to +8°C
	For generic drugs (me-too Status)	TYPHIBEV Typhoid Conjugate Vaccine, M & M Pharma, Lahore, Registration #: 107935
	Pharmacotherapeutic Group of (API)	Typhoid Conjugate Vaccine
	Name, address of Manufacturing site:	PT Bio Farma (Persero)-Jl. Pasteur No. 28, Bandung, 40161-Indonesia
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	PT Bio Farma (Persero), Jl. Pasteur No. 28, Bandung, 40161, Indonesia
	Details of Certificates (CoPP/FSC/cGMP):	CoPP indicates GMP Status
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies were conducted on three batches of each bulk. Vi bulk was studied for 3 years at −20°C, with the dossier concluding stability for 24 months; accelerated stability at 2–8°C for 6 months was also satisfactory. Vi-DT bulk was studied for 3 years at 2–8°C, with the dossier concluding that it remained stable for 3 years; accelerated studies at 25±2°C and 37±1°C for 6 months were reported as satisfactory.
	The status in reference regulatory authorities	WHO Prequalified status of the same formulation (SKYTyphoid Multi Inj.) is provided (Link:

		https://extranet.who.int/prequal/vaccines/p/skytypl multi-inj)
	Evaluation Remarks	
	Based on the submitted quality, non-clinical and clinical data, BIO-TCV demonstrates acceptable quality, satisfactory immunogenicity and a favorable safety profile, with no significant safety concerns identified. The manufacturing process is adequately controlled and validated, and the stability data support the proposed storage condition and shelf life. Overall, the benefit–risk profile is considered favorable; therefore, BIO-TCV may be recommended for registration.	
	Decision	
	Approved Keeping in view the approval of vaccine in country of origin, Registration Board approved the product as per Import Policy for Finished Drugs.	
94	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Amson Vaccines & Pharma (Pvt.) Ltd** Plot # 115, Industrial Triangle Kahuta Road **(017/DSL(D)/PS&DC-ICT/2025)**
	Application Form Dy. No / Tracking ID & date of submission	(HUE-L1W-JYTQ, 2026-08-16)
	Detail of Fee Submitted	313500, 2026-03-11,
	The proposed proprietary name / brand name	**BIO-TCV Injection 5ml (10 Doses)**
	Label Claim	Each 0.5ml dose contains: Typhoid vi polysaccharide conjugated to Diphtheria Toxoid .....25 mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Box, 10 vials @ 10 doses (5 mL) -As per SRO
	Shelf Life (Unit)	2 Year(s)+2 to +8°C
	For generic drugs (me-too Status)	TYPHIBEV Typhoid Conjugate Vaccine, M & M Pharma, Lahore, Registration #: 107935
	Pharmacotherapeutic Group of (API)	Typhoid Conjugate Vaccine
	Name, address of Manufacturing site:	PT Bio Farma (Persero)-Jl. Pasteur No. 28, Bandung, 40161-Indonesia
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	PT Bio Farma (Persero), Jl. Pasteur No. 28, Bandung, 40161, Indonesia
	Details of Certificates (CoPP/FSC/cGMP):	CoPP Indicates GMP Status
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies were conducted on three batches of each bulk. Vi bulk was studied for 3 years at –20°C, with the dossier concluding stability for 24 months; accelerated stability at 2–8°C for 6 months was also satisfactory. Vi-DT bulk was studied for 3 years at 2–8°C, with the dossier concluding that it remained stable for 3 years; accelerated studies at 25±2°C and 37±1°C for 6 months were reported as satisfactory
	The status in reference regulatory authorities	WHO Prequalified status of the same formulation (SKYTyphoid Multi Inj.) is provided (Link: https://extranet.who.int/prequal/vaccines/p/skytypl multi-inj)

Evaluation Remarks
Based on the submitted quality, non-clinical and clinical data, BIO-TCV demonstrates acceptable quality, satisfactory immunogenicity and a favorable safety profile, with no significant safety concerns identified. The manufacturing process is adequately controlled and validated, and the stability data support the proposed storage condition and shelf life. Overall, the benefit–risk profile is considered favorable; therefore, BIO-TCV may be recommended for registration.
Decision
Approved Keeping in view the approval of vaccine in country of origin, Registration Board approved the product as per Import Policy for Finished Drugs.

Case No. 1: Imported Veterinary Biologicals applied by M/s Hivet Animal Health Business, Lahore applied in hard and resubmitted via E-App CMS tracking ID: VY5-XL7-6ERL.

Sr. No.	Name of Manufacturer	Brand Name & Composition	Pack Size, Shelf Life & Storage Condition	Date of Application & Fee Details
1.	**MAH:** PT. VAKSINDO SATWA NUSANTARA Wisma Millenia, Jl. MT Haryono Kav. 16 Jakarta-Indonesia **Manufacturer:** M/s PT. VAKSINDO SATWA NUSANTARA JI. Mercedes Benz No. 12, Cicadas, Gunung Putri, Bogor, West Java 16964, Indonesia.	**VAKSIMUNE ND Inaktif Inactivated vaccine of Newcastle Disease virus of LaSota strain, in the form of oil emulsion** Each dose contain: ND virus of the LaSota strain, inactivated Virus titer (pre inactivation) is at least..... $10^{8.3}EID_{50}$	1000 Doses/ 500ml Vial 24 months (2^0C-8^0C)	Dy. No. 1186 date of submission; 13/1/ 2022 Challan no. 182725875 Dated' 19/12/2022, Rs.150,000
2.		**VAKSIMUNE ND IB Inaktif Combined inactivated vaccine of Newcastle Disease (ND) LaSota strain and Infectious Bronchitis (IB) Massachusetts-41 strain in oil emulsion**) Each dose contain: ND virus of the LaSota strain, inactivated Virus titer (pre inactivation) is at least.....$10^{8.3}EID_{50}$ IB virus of Massachusetts - 41 strain, inactivated (pre inactivation) is at least.....$10^{7.0}EID_{50}$	1000 Doses/ 500ml Vial 24 months (2^0C-8^0C)	Dy. No. 1185 date of submission; 13/1/ 2022 Challan no. 1310505014 Dated' 19/12/2022, Rs.150,000

The applications were deferred in 336th meeting of Registration Board for following:

- Submission of FSC showing the composition of the applied product.
- Revision of Label mentioning complete address of the manufacturing site at the label.
- The Master seed is taken from Lasher Associated Inc. USA, while the finished form is manufactured and released by PT. Vaksindo Satwa Nusantara, INDONESIA. Justification of safety of master seed and evidence for GMP of manufacturing site is required.

The firm has submitted the following:

- FSCs of both products indicating composition of products.
- Revised label mentioning complete address of the manufacturing site.
- GMP Certificate of manufacturer.

Observations:

i. The FSC of VAKSIMUNE ND Inaktif is not Apostille/ Legalized.
ii. FSCs of both products are mentioning Free Sale status as admitted for sale instead of indicating actual status of availability of product.

Decision:

Keeping in view GMP and FSC; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of valid Apostille/ Legalized FSCs for both products indicating actual availability of product in country of origin.

Case No. 02: Locally manufactured veterinary vaccine applied by M/s Intervac Pvt. Ltd., Sheikhupura.

Name of Manufacturer	Brand Name & Composition	Pack Size & Shelf Life	Receiving & Fee Details
M/S Intervac (Pvt.) Ltd, 18KM Lahore Sheikhupura Road, Sheikhupura	Intervac Polyvalent Mastitis vaccine Each 0.5ml dose contains: Inactivated Staphylococcus aureus…..5 x 10^{10} cells Inactivated Streptococcus uberis…….5 x 10^{10} cells Inactivated Escherichia coli…..5 x 10^{10} cells	50ml, 100ml & 300ml Vial 1 Year (2^0C-8^0C)	R&I dated 14-02-2024 Fee Rs. 30,000/- dated 29-11-2023.

The firm has submitted application on Form-5 along with stability study data of one batch for one month. The firm needs to include Potency & Safety tests in its Finished Product Specifications and need to perform all the tests during stability studies as included in specifications.

Licensing division has communicated the decision of CLB regarding availability of viral and bacterial vaccine sections of the firm. The Licensing Division has not explained whether the above sections are for live or inactivated vaccines. Moreover, they also informed that firm has applied for regularization of layout plan for which inspection shall be conducted by the Licensing Division.

Decision:

Keeping in view recommendation of veterinary expert member; Registration Board deferred the case for submission of following by the firm:

i. **Quality data including Chemistry, Manufacturing & Control of 03 trial batches of finished product.**
ii. **Immunological relevance and need of applied product for Pakistan.**

Case No. 03: Virtual Inspection of Manufacturer Abroad for Veterinary Vaccine applied by M/s Pharmakon International Enterprises, Islamabad approved in 347th meeting of Registration Board.

Following product of M/s Pharmakon International Enterprises, Islamabad was approved in 347th meeting of Registration Board as per following details:

Name of Manufacturer	Brand Name & Composition	Decision of RB in 347th Meeting
M/s. Hester Biosciences Africa Limited-Plot No. 647 & 648, Tamco Industrial Estate, Kibaha Tanzania.	**PESTE DES PETITS RUMINANTS VACCINE,** Live Nigerian 75/1 Strain PESTE DES PETITS RUMINANTS VIRUS, Live Nigerian 75/1 Strain…….Not Less Than (NLT) $1\times10^{2.5}$ CCU_{50}.	*Keeping in view the legalized FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and submission of valid legalized GMP certificate of the manufacturer abroad by the applicant.*

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- Mr. Zubair Masood, Deputy Director (BE&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;

Observations	Potential GMP Impact
Common blending area used for mixing all types of vaccines, including bacterial, viral, live, and killed/inactivated vaccines.	Increases the risk of cross-contamination and mix-ups between different vaccine types and microorganisms.
Vaccine mixing room also used for preparation/mixing of diluent, which is non-biological.	Use of the same area for vaccine and diluent may lead to contamination, cleaning validation challenges, and increased risk of carryover residues.
Common filling line used for live virus vaccines and live bacterial vaccines.	Sharing of the same filling line for different live organisms creates a high risk of cross-contamination and potential contamination of one product with another live microorganism. This can adversely affect product quality, patient safety, and compliance with GMP requirements.
Vials transferred from DHS unloading area to filling area using open trolleys.	Open transfer of sterilized vials exposes them to the surrounding environment, increasing the risk of particulate and microbial contamination prior to filling. This practice may compromise sterility and indicates inadequate protection during material transfer.
Complete HVAC validation covering all required parameters is not provided.	Incomplete HVAC validation demonstrates inadequate qualification and monitoring of critical environmental control systems. Lack of documented evidence for parameters such as temperature, humidity, differential pressure, recovery, air flow pattern, and viable/non-viable particle control may result in non-compliance with GMP requirements and reduced confidence in cleanroom performance and contamination prevention.
Performance Qualification (PQ) reports Phase 1 and Phase 2 is provided only that had been conducted in the year 2021 with no Phase III/ongoing verification evidence.	Absence of ongoing monitoring evidence indicates insufficient lifecycle validation of the water system. This reduces assurance that the system consistently performs within qualified parameters over time.

2. Conclusion

Based on the virtual inspection of **M/s Hester Biosciences Africa Limited-Plot No. 647 & 648, Tamco Industrial Estate, Kibaha Tanzania** 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 Live attenuated virus vaccines is **not recommended** because of the critical observations contained in paragraph 7.

PESTE DES PETITS RUMINANTS VACCINE, Live Nigerian 75/1 Strain
PESTE DES PETITS RUMINANTS VIRUS, Live Nigerian 75/1 Strain…….Not Less Than (NLT) $1\times10^{2.5}$ CCU_{50}.

Registration Board in its 360th meeting decided as follows:

"*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.*"

Letter has been issued to the firm to appear before the Board.

Proceedings of the Board:

Dr. Faisal Rasheed, Quality Manager & Dr. Ahad Fayyaz, Technical Manager appeared before the Board on behalf of applicant and informed that the manufacturer abroad wants to give clarifications about the observations of panel. The Board asked the representatives whether they have any documentary evidence against the observations of panel. The representatives submitted that they don't have the documents with them at that time, however, they will submit shortly. The representatives of the applicant did not submit any documentary response of the observations of panel of inspectors of DRAP even till the preparation of minutes of meeting.

Decision:

Keeping in view the observations of panel of inspectors of DRAP and proceedings of the Board; Registration Board rejected the application of PESTE DES PETITS RUMINANTS VACCINE applied by M/s Pharmakon International Enterprises, Islamabad on the following grounds:-

i. **Common blending area used for mixing all types of vaccines, including bacterial, viral, live, and killed/inactivated vaccines.**
ii. **Vaccine mixing room also used for preparation/mixing of diluent, which is non-biological.**
iii. **Common filling line used for live virus vaccines and live bacterial vaccines.**
iv. **Vials transferred from DHS unloading area to filling area using open trolleys.**
v. **Complete HVAC validation covering all required parameters is not provided.**
vi. **Performance Qualification (PQ) reports Phase 1 and Phase 2 is provided only that had been conducted in the year 2021 with no Phase III/ongoing verification evidence.**

Case No. 4: REQUEST FOR EXTENSION OF VALIDITY OF APPROVAL FOR ADDITIONAL MANUFACTURING SITE FOR HUMAN INSULIN VIALS.

M/s Novo Nordisk Private Limited Karachi, has submitted a request through DRAP e-App System vide Tracking ID LLW-LWV-8ADY dated 1st July 2026 for approval of additional Manufacturing Site for Human Insulin Vials, granted vide DRAP Approval Letters dated 06.12.2024 and 11.12.2024, for following registered products.

Sr. No.	Brand Name	Registration No.	Existing Approved Mfg. Site	Additional Approved Mfg. Site
1.	Actrapid HM Vial	010204	Novo Nordisk Production SAS, 45 Avenue d'Orleans, F-	Eskayef Pharmaceuticals Limited, 400 Squibb Road,
2.	Insulatard HM Vial	010205		

			28000 Chartres, France	Tongi Industrial Area, Tongi, Ghazipur 1711, Bangladesh.
3.	Mixtard 30 HM Vial	010348		

The Appellate Board in its 165th meeting held on 23-05-2024 against the decision of the Registration Board regarding approval of additional manufacturing site for above biological products decided as under:

a. *The Appellant may import Actrapid HM 100IU/ml, 10ml Vial, Human Insulin Regular (rDNA) and Insulatard HM 100/ U/ml, 10ml vial Human Insulin isophane (rDNA) from both sites. However, approval of additional manufacturing site namely M/s Eskayef Pharmaceutical Limited, 400 Squibb Road, Tongi Industrial Area Tongi Ghazipur 1711 Bangladesh shall be valid for two years to alleviate the shortage of insulin in market;*
b. *The Appellant shall ensure the safety. quality and efficacy of the insulin manufactured at the additional site in Bangladesh.*
c. *The Appellant and/or its Foreign Principal shall explore manufacturing of insulin in Pakistan within a period of two years either directly or through contract manufacturing as they are already doing in Bangladesh. This will address the concern* of any shortage of insulin for which the Appellant is seeking additional site.

Accordingly, the approval of additional manufacturing i.e., Eskayef Pharmaceuticals Limited, 400 Squibb Road, Tongi Industrial Area, Tongi, Ghazipur 1711, Bangladesh for manufacturing above mentioned insulins was granted by Registration Board 332nd and 339th meeting and communicated by BE&R Division vide DRAP letter dated 6 & 11 December 2024.

Decision:

Registration Board deffered the case update on following conditions which were part of the approval of additional site:-

a. ***The Appellant shall ensure the safety. quality and efficacy of the insulin manufactured at the additional site in Bangladesh.***
b. ***The Appellant and/or its Foreign Principal shall explore manufacturing of insulin in Pakistan within a period of two years either directly or through contract manufacturing as they are already doing in Bangladesh. This will address the concern* of any shortage of insulin for which the Appellant is seeking additional site.**

Case No. 5: Change in the Manufacturing Process of the Finished Drug product i.e. Grafalon (Anti T-Lymphocyte Globulin) Injection (Reg. No. 033134)

M/s Allmed Laboratories Karachi has submitted application vide TID: BA2-2T4-P472 regarding the change in manufacturing process of their subject mentioned registered product. The firm submitted that The proposed change falls under Clause MaV-11 – Major Change in the Manufacturing Process of the Finished Drug Product of the DRAP Post-Registration Variation (PRV) Guidelines the applicable requirements and conditions specified under the PRV Guidelines have been fulfilled. The proposed manufacturing changes have also been reviewed and approved by the competent regulatory authority in Germany, the Paul-Ehrlich-Institut (PEI), through the applicable European regulatory procedure.

Grafalon® (Anti T-Lymphocyte Globulin; ATG) is a concentrated and highly purified polyclonal anti-human T-lymphocyte immunoglobulin derived from rabbit serum following immunization with the human T-lymphoblast cell line Jurkat. The manufacturing process comprises production of the immunogen, immunization of rabbits, collection and purification of immunoglobulin from rabbit serum, subsequent drug substance/drug product processing, and final filling and finishing operations.

The proposed variation comprises the following changes to the manufacturing process of the finished drug product:

1. **Homogenization:** Replacement of manual plunger mixing with an integrated bottom-mounted magnetically coupled stirrer (50–150 rpm; 157–360 seconds).
2. **Virus filtration:** Replacement of **Viresolve® NFP** with **Viresolve® Pro** due to discontinuation/supply termination of the existing filter.

The following data/documentation have been submitted:

i. Detailed description and justification of the proposed manufacturing changes.
ii. Process validation data from three consecutive commercial-scale batches (25–58 kg).
iii. Virus clearance/validation study for Viresolve® Pro, including HAV, PPV, BVDV and Reo-3.
iv. Process parameters and validation data for the revised homogenization/mixing step.
v. Stability data for development batch.
vi. Regulatory approval/PACMP documentation from the Paul-Ehrlich-Institute/European regulatory authorities.
vii. Process validation report, including pooling, protein concentration adjustment, nanofiltration and final 0.2 µm filtration.
viii. Fee payment evidence (Challan No. 64113181, Rs. 12,530/-).

Submitted please.

Decision:

1. **The Registration Board approved the above-mentioned variations pertaining to the change in the manufacturing process, i.e. Homogenization and Virus Filtration, in respect of M/s Allmed Laboratories, Karachi, for Grafalon (Anti-T-Lymphocyte Globulin) Injection (Reg. No. 033134).**
2. **The Board further authorized its Chairman to approve all post-registration variations relating to changes in manufacturing processes.**

Case No. 06: Virtual Inspection of Manufacturer Abroad for Veterinary Vaccines applied by M/s Agriprom Pakistan (Pvt.) Ltd., Lahore approved in 347th meeting of Registration Board.

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

Name of Manufacturer	Brand Name & Composition	Pack Size & Shelf Life	Decision of RB in 347th Meeting
M/s. Beijing Centrebio Biology Co., Ltd.-No. 44, Yongda Road, Daxing bio-medicine Industrial, Base, Zhongguancun Science Park, Daxing District, Beijing-China.	CENTRE-NDFLU H9 Each dose (0.5 ml) contains: Minimum concentration of Avian Newcastle Disease Virus, LaSota strain ... 10^8.175 EID50 Minimum concentration of Avian Influenza (subtype H9) Virus, WD strain ... 10^7.175 EID50	250ml/500 doses 18 months (2^0C -8^0C)	Keeping in view the legalized GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.
	CENTRE-NIEA H9 Each dose (0.5 ml) of vaccine contains: Newcastle Disease Virus, Strain La Sota	250ml/500 doses 18 months (2^0C -8^0C)	Keeping in view the legalized GMP & FSC indicating product availability in the country of origin, the

	≥ 10^8.5 EID50 Infectious Bronchitis Virus, Strain M41 ..... ≥ 10^6.5 EID50 Egg Drop Syndrome Virus, Strain HSH23 ..... ≥ 1000 HA units Avian Influenza (subtype H9) Virus, Strain WD ..... ≥ 10^7.5 EID50		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 ..... ≥ 10^8.5 EID50

Infectious Bronchitis Virus, Strain M41 ..... ≥ 10^6.5 EID50

Egg Drop Syndrome Virus, Strain HSH23 ..... ≥ 1000 HA units

Avian Influenza (subtype H9) Virus, Strain WD ..... ≥ 10^7.5 EID50

Decision of 353rd meeting:

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

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

Proceedings of 354th Meeting:

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

i. Dr. Ali Aun
ii. Dr. Ahsan

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

Decision of 354th Meeting:

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

Decision of 357th meeting:

Registration Board deferred to seek opinion of Licensing Division of DRAP regarding the current regulatory practice and requirement (local manufacturing) for granting same/dedicated manufacturing sections for Killed or live bacterial or viral vaccines under the Drugs (Licensing, Registering & Advertising) Rules, 1976 so that there shall be no discrimination in the manufacturing requirement of imported and locally manufactured products.

Opinion of Licensing Division of DRAP shall be placed in Expert Working Group on Veterinary Drugs for discussion.

Remarks of BE&R:

The case was referred to the Licensing Division, DRAP, for soliciting its comments and opinion. The comments of the Licensing Division are reproduced below:

"As per Drug (L, R&A) Rules section 5.2 of schedule adopted under compliance framework circular document-II for PIC/s adaptation vide circular No.6-1/2026-Lic(M-314) dated 24-02-2026.

Dedicated facilities for production

Dedicated and self-contained facilities for the production of particular drugs shall be provided in addition to the general facilities such as highly sensitizing materials (e.g., penicillin) or biological preparations (e.g., live microorganisms) or cytotoxic substances or radiopharmaceutical or veterinary immunological preparations or sterile products or for that matter such other highly active pharmaceutical products, antibiotics, hormones as may be identified by the Central Licensing Board at any stage in order to minimize the risk of a serious medical hazard due to cross-contamination. Veterinary products containing ingredients similar to those used for human health and of the same quality can be manufactured in the same premises used for manufacture of pharmaceutical. Products, however,

simultaneously human drugs shall not be manufactured. Non-pharmaceutical products, technical positions, such as pesticides shall not be manufactured in the same premises already used for the manufacture of pharmaceutical products. In exceptional cases of emergency, the principle of campaign working in the same facilities may be allowed by the Central Licensing Board provided that specific precautions are taken and the necessary validations are made.

Moreover, the WHO TRS 999 regarding manufacturing of Vaccine is as under.

9.3 Killed vaccines, antisera and other biological products – including those made by rDNA techniques, toxoids and bacterial extracts – may, following inactivation, be manufactured on the same premises provided that adequate decontamination and cleaning measures are implemented on the basis of QRM.

10.3 Dedicated production areas should be used for the handling of live cells capable of persistence in the manufacturing environment, for pathogenic organisms of Biosafety Risk Group 3 or 4 and/or for spore-forming organisms until the inactivation process is accomplished and verified. For Bacillus anthracis, Clostridium tetani and Clostridium botulinum strictly dedicated facilities should be utilized for each individual product. Up-to-date information on these and other high-risk or "special" agents should be sought from major information resources (27). Where campaign manufacture of spore-forming organisms occurs in a facility or suite of facilities only one product should be processed at any one time. Use of any pathogenic organism above Biosafety Risk Group 3 may be permitted by the NRA according to the biohazard classification of the organism, the risk assessment of the biological product and its emergency demand.

Above documents may be taken in consideration. Submitted please."

Decision of 360th meeting:

Registration Board deferred the case for further deliberation.

Remarks by BE&R:

The case was referred to the Licensing Division for furnishing a conclusive opinion in the light of indigenous manufacturing. The comments of the Licensing Division are reproduced below:

"It is submitted that the mater on indigenous manufacturing of Biologicals and Vaccines may be considered keeping in view the historical conversion of GMP from administrative prospective to more scientific and in line with current requirements of PIC/s and WHO.

Previous Prospective

The Drug (L,R&A) rules 1976 were promulgated in 1976 with the available standard manufacturing practices at that time which were more toward the administrative division of biological sections , In 1998 the Than Drug Control Administration (DCA) adopted WHO guidelines which were translated as schedule -B (GMP requirements) as part of conditions of Drug manufacturing License. In those WHO adopted GMP guidelines section 5.2, The dedication was meant of manufacturing facility for biological drugs/preparation of live organisms) . therefore the only division of vaccine depend upon the criteria weather the finished product contain live micro organism which includes bacteria. Virus or protozoa at the level of LOP approval and grant of DML.

Current Prospective

In 2025 DRAP issued S.R.O. 1587(I)/2025 and adopted Pharmaceutical Inspection Co-operation Scheme (PIC/S) guidelines , which was officially become the condition of license from 25 Feb 2026.CLB adoteted a more scientific approach of transitional adaptation/switching from previous to current GMP standard in

phase wise manner, Therefore previous standards will remain enforced till adaptation of PIC/s GMP guidelines regarding chapter 3 related to premises and equipment, however this process does not bars any local or foreign manufacturer for voluntarily adopting the current full PIC/s and WHO GMP guidelines . Therefore while considering the product specific inspection of a vaccine in foreign facility , if the manufacturer claims that he has adopted PIC/s Guidelines than the general requirement of premises and equipment as sated in chapter 3.6 as under may be considered

" Production Area

Cross-contamination should be prevented for all products by appropriate design and operation of manufacturing facilities. The measures to prevent cross contamination should be commensurate with the risk

Dedicated facilities are required for manufacturing when a medicinal product presents a risk because:

i. the risk cannot be adequately controlled by operational and/ or technical measures,

ii. scientific data from the toxicological evaluation does not support a controllable risk (e.g. allergenic potential from highly sensitizing materials such as beta-lactams) or

iii. relevant residue limits, derived from the toxicological evaluation, cannot be satisfactorily determined by a validated analytical method.

Further PIC/s has published a specific guideline as Annexure 2b for MANUFACTURE OF BIOLOGICAL MEDICINAL SUBSTANCES AND PRODUCTS FOR HUMAN USE , where in the matter of dedication of premises id also addressed in chapter of PREMISES AND EQUIPMENT stating that

7. Dedicated production areas should be used for the handling of live cells. Dedicated production area should be used for the manufacture of pathogenic organisms (i.e. Biosafety level 3 or 4).

8. Manufacture in a multi-product facility may be acceptable where the following, or equivalent (as appropriate to the product types involved) considerations and measures are part of an effective control strategy to prevent cross-contamination:

(a) Knowledge of key characteristics of all cells, organisms and any adventitious agents (e.g. pathogenicity, detectability, persistence, susceptibility to inactivation) within the same facility.

(b) Where production is characterized by multiple small batches from different starting materials, factors such as the health status of donors and the risk of total loss of product should be taken into account when considering the acceptance of concurrent working during development of the control strategy.

(c) Live organisms and spores are prevented from entering non-related areas or equipment by addressing all potential routes of cross-contamination and utilizing single use components and engineering measures such as closed systems. (d) Control measures to remove the organisms and spores before the subsequent manufacture of other products, these control measures should also take the heating, ventilation and air conditioning (HVAC) system into account. Cleaning and decontamination for the organisms and spores should be validated.

(e) Environmental monitoring, specific for the micro-organism being manufactured, where the micro-organisms are capable of persistence in the manufacturing environment and where methods are available, is conducted in adjacent areas during manufacture and after completion of cleaning and decontamination. Attention should also be given to risks arising with use of certain monitoring equipment (e.g. airborne particle monitoring) in areas handling live and/or spore forming organisms.

(f) Products, equipment, ancillary equipment (e.g. for calibration and validation) and disposable items are only moved within and removed from such areas in a manner that prevents contamination of other areas, other products and different product stages (e.g. prevent contamination of inactivated or toxoided products with non-inactivated products).

(g) Campaign based manufacturing.

Conclusion

Keeping in view the above historic prospective , the over view of current international best practices like PIC/s and WHO , if the manufacturing facility is following the administrative division of sections than dedication of manufacturing facility/premises as mentioned in section 5.2 of schedule B is more appropriate which give division (Stand along building) on the basis of handling of live microorganism however if the manufacturer claims to be or to have adopted PIC/s and WHO Guidelines than multiproduct facility may be acceptable along with all conditions of dedication and contamination contamination Control Strategy (CCS) as a major part of QRM (Quality Risk Management) as mentioned in point no.8

Note : Above comments reflects the current thinking of this division and may further be reviewed by competent authority (Drug Registration Board) before granting approval of Vaccine upon conduct of product specific inspection."

Decision of 361st meeting:

Registration Board decided to refer the case for further deliberations.

Case No. 07: Virtual Inspection of Manufacturer Abroad for Veterinary Vaccines applied by M/s Hi Tech Pharmaceuticals I-C Shadman Chowk Jail Road Lahore approved in 347th meeting of Registration Board.

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

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

One dose (0.5 ml) contains;

Inactivated antigens in the titer before inactivation:

Salmonella enteritidis strain SE-15 at least 10^8 CFU

Salmonella typhimurium strain ST-15 at least 10^8 CFU

Salmonella gallinarum strain SG-15 at least 10^8 CFU

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

Each dose contains:

Newcastle disease, strain Hitchner B1 ≥ 10^6 EID50

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

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

Each dose (1ml) contains:

Fowl pox virus, strain Cutter ≥ 10^2.8 TCID50

Solvent contains:

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

Brilliant blue dye E 133 - 0.5 g

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

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

Each one dose contains:

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

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

One dose of the vaccine contains;

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

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

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

Each dose (0.1 ml) contains:

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

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

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

Following are the observations & conclusion of Panel:

Observation

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

Observations	**Impact on quality and GMP compliance**
The firm has provided a common production area for the manufacture of inactivated viral and bacterial vaccines. Antigen production activities are carried out in separate, dedicated production lines; however, the emulsification and filling operations for finished product manufacturing are performed within the same area.	The use of a shared area for emulsification and filling of different vaccine types (viral and bacterial) does not ensure adequate segregation of operations, increasing the potential risk of cross-contamination and mix-ups. This practice is not in compliance with GMP requirements for the physical and operational segregation of processes involving different biological products.
The firm has one live bacterial vaccine among its registered products. Upon inquiry, the firm stated that this product is manufactured once per year and that no segregated area is available for live bacterial vaccine production. Instead, mixing of the live bacterial vaccine is carried out in the Antigen Preparation Room (1-2107). For filling operations, a semi-automatic filling machine installed in the live virus vaccine mixing room (1-2133) is used,	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.**

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

Conclusion

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

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

One dose (0.5 ml) contains;

Inactivated antigens in the titer before inactivation:

Salmonella enteritidis strain SE-15 at least 10^8 CFU

Salmonella typhimurium strain ST-15 at least 10^8 CFU

Salmonella gallinarum strain SG-15 at least 10^8 CFU

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

Each dose contains:

Newcastle disease, strain Hitchner B1 ≥ 10^6 EID50

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

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

Each dose (1ml) contains:

Fowl pox virus, strain Cutter ≥ 10^2.8 TCID50

Solvent contains:

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

Brilliant blue dye E 133 - 0.5 g

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

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

Each one dose contains:

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

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

One dose of the vaccine contains;

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

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

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

Each dose (0.1 ml) contains:

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

Decision of 353rd meeting:

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

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

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

Proceedings of 354th meeting:

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

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

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

Decision of 354th Meeting:

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

Decision of 357th meeting:

Registration Board deferred to seek opinion of Licensing Division of DRAP regarding the current regulatory practice and requirement (local manufacturing) for granting same/dedicated manufacturing sections for Killed or live bacterial or viral vaccines under the Drugs (Licensing, Registering & Advertising) Rules, 1976 so that there shall be no discrimination in the manufacturing requirement of imported and locally manufactured products.

Opinion of Licensing Division of DRAP shall be placed in Expert Working Group on Veterinary Drugs for discussion.

Remarks of BE&R:

The case was referred to the Licensing Division, DRAP, for soliciting its comments and opinion. The comments of the Licensing Division are reproduced below:

"As per Drug (L, R&A) Rules section 5.2 of schedule adopted under compliance framework circular document-II for PIC/s adaptation vide circular No.6-1/2026-Lic(M-314) dated 24-02-2026.

Dedicated facilities for production

Dedicated and self-contained facilities for the production of particular drugs shall be provided in addition to the general facilities such as highly sensitizing materials (e.g., penicillin) or biological preparations (e.g., live microorganisms) or cytotoxic substances or radiopharmaceutical or veterinary immunological preparations or sterile products or for that matter such other highly active pharmaceutical products, antibiotics, hormones as may be identified by the Central Licensing Board at any stage in order to minimize the risk of a serious medical hazard due to cross-contamination. Veterinary products containing ingredients similar to those used for human health and of the same quality can be manufactured in the same premises used for manufacture of pharmaceutical. Products, however, simultaneously human drugs shall not be manufactured. Non-pharmaceutical products, technical positions, such as pesticides shall not be manufactured in the same premises already used for the manufacture of pharmaceutical products. In exceptional cases of emergency, the principle of campaign working in the same facilities may be allowed by the Central Licensing Board provided that specific precautions are taken and the necessary validations are made.

Moreover, the WHO TRS 999 regarding manufacturing of Vaccine is as under.

9.3 Killed vaccines, antisera and other biological products – including those made by rDNA techniques, toxoids and bacterial extracts – may, following inactivation, be manufactured on the same premises provided that adequate decontamination and cleaning measures are implemented on the basis of QRM.

10.3 Dedicated production areas should be used for the handling of live cells capable of persistence in the manufacturing environment, for pathogenic organisms of Biosafety Risk Group 3 or 4 and/or for spore-forming organisms until the inactivation process is accomplished and verified. For Bacillus anthracis, Clostridium tetani and Clostridium botulinum strictly dedicated facilities should be utilized for each individual product. Up-to-date information on these and other high-risk or "special" agents should be sought from major information resources (27). Where campaign manufacture of spore-forming organisms occurs in a facility or suite of facilities only one product should be processed at any one time. Use of any pathogenic organism above Biosafety Risk Group 3 may be permitted by the NRA according to the biohazard classification of the organism, the risk assessment of the biological product and its emergency demand.

Above documents may be taken in consideration. Submitted please."

Decision of 360th meeting:

Registration Board deferred the case for further deliberation.

Remarks by BE&R:

The case was referred to the Licensing Division for furnishing a conclusive opinion in the light of indigenous manufacturing. The comments of the Licensing Division are reproduced below:

“It is submitted that the mater on indigenous manufacturing of Biologicals and Vaccines may be considered keeping in view the historical conversion of GMP from administrative prospective to more scientific and in line with current requirements of PIC/s and WHO.

Previous Prospective

The Drug (L,R&A) rules 1976 were promulgated in 1976 with the available standard manufacturing practices at that time which were more toward the administrative division of biological sections , In 1998 the Than Drug Control Administration (DCA) adopted WHO guidelines which were translated as schedule -B (GMP requirements) as part of conditions of Drug manufacturing License. In those WHO adopted GMP guidelines section 5.2, The dedication was meant of manufacturing facility for biological drugs/preparation of live organisms) . therefore the only division of vaccine depend upon the criteria weather the finished product contain live micro organism which includes bacteria. Virus or protozoa at the level of LOP approval and grant of DML.

Current Prospective

In 2025 DRAP issued S.R.O. 1587(I)/2025 and adopted Pharmaceutical Inspection Co-operation Scheme (PIC/S) guidelines , which was officially become the condition of license from 25 Feb 2026.CLB adoteted a more scientific approach of transitional adaptation/switching from previous to current GMP standard in phase wise manner, Therefore previous standards will remain enforced till adaptation of PIC/s GMP guidelines regarding chapter 3 related to premises and equipment, however this process does not bars any local or foreign manufacturer for voluntarily adopting the current full PIC/s and WHO GMP guidelines . Therefore while considering the product specific inspection of a vaccine in foreign facility , if the manufacturer claims that he has adopted PIC/s Guidelines than the general requirement of premises and equipment as sated in chapter 3.6 as under may be considered

" Production Area

Cross-contamination should be prevented for all products by appropriate design and operation of manufacturing facilities. The measures to prevent cross contamination should be commensurate with the risk

Dedicated facilities are required for manufacturing when a medicinal product presents a risk because:

i. the risk cannot be adequately controlled by operational and/ or technical measures,

ii. scientific data from the toxicological evaluation does not support a controllable risk (e.g. allergenic potential from highly sensitizing materials such as beta-lactams) or

iii. relevant residue limits, derived from the toxicological evaluation, cannot be satisfactorily determined by a validated analytical method.

Further PIC/s has published a specific guideline as Annexure 2b for MANUFACTURE OF BIOLOGICAL MEDICINAL SUBSTANCES AND PRODUCTS FOR HUMAN USE , where in the matter of dedication of premises id also addressed in chapter of PREMISES AND EQUIPMENT stating that

7. Dedicated production areas should be used for the handling of live cells. Dedicated production area should be used for the manufacture of pathogenic organisms (i.e. Biosafety level 3 or 4).

8. Manufacture in a multi-product facility may be acceptable where the following, or equivalent (as appropriate to the product types involved) considerations and measures are part of an effective control strategy to prevent cross-contamination:

(a) Knowledge of key characteristics of all cells, organisms and any adventitious agents (e.g. pathogenicity, detectability, persistence, susceptibility to inactivation) within the same facility.

(b) Where production is characterized by multiple small batches from different starting materials, factors such as the health status of donors and the risk of total loss of product should be taken into account when considering the acceptance of concurrent working during development of the control strategy.

(c) Live organisms and spores are prevented from entering non-related areas or equipment by addressing all potential routes of cross-contamination and utilizing single use components and engineering measures such as closed systems. (d) Control measures to remove the organisms and spores before the subsequent manufacture of other products, these control measures should also take the heating, ventilation and air conditioning (HVAC) system into account. Cleaning and decontamination for the organisms and spores should be validated.

(e) Environmental monitoring, specific for the micro-organism being manufactured, where the micro-organisms are capable of persistence in the manufacturing environment and where methods are available, is conducted in adjacent areas during manufacture and after completion of cleaning and decontamination. Attention should also be given to risks arising with use of certain monitoring equipment (e.g. airborne particle monitoring) in areas handling live and/or spore forming organisms.

(f) Products, equipment, ancillary equipment (e.g. for calibration and validation) and disposable items are only moved within and removed from such areas in a manner that prevents contamination of other areas, other products and different product stages (e.g. prevent contamination of inactivated or toxoided products with non-inactivated products).

(g) Campaign based manufacturing.

Conclusion

Keeping in view the above historic prospective , the over view of current international best practices like PIC/s and WHO , if the manufacturing facility is following the administrative division of sections than dedication of manufacturing facility/premises as mentioned in section 5.2 of schedule B is more appropriate which give division (Stand along building) on the basis of handling of live microorganism however if the manufacturer claims to be or to have adopted PIC/s and WHO Guidelines than multiproduct facility may be acceptable along with all conditions of dedication and contamination contamination Control Strategy (CCS) as a major part of QRM (Quality Risk Management) as mentioned in point no.8

Note : Above comments reflects the current thinking of this division and may further be reviewed by competent authority (Drug Registration Board) before granting approval of Vaccine upon conduct of product specific inspection."

Decision of 361st meeting:

Registration Board decided to defer the case for further deliberation.

Case No. 08: Virtual Inspection of Manufacturer Abroad for Biological product applied by M/s Aspire Life Sciences (Private) Limited, Jhelum approved in 352nd meeting of Registration Board.

Following product of M/s Aspire Life Sciences (Private) Limited Street No. 2, Rehman Colony, Opposite Old Sadar Thana Tehsil Road, Jhelum was approved in 352nd meeting of Registration Board as per following details:

Name of Manufacturer	Brand Name & Composition	Decision of 352nd meeting
M/s SHREE VENKATESH INTERNATIONAL LIMITED, Block No. 311, Kosamba Pardi Road, Village: Nandav, Taluka: Mangrol, Dist. Surat – 394125, Gujarat-INDIA.	**Ovigil GP 5000IU** 2ml Vial of Chorionic Gonadotrophin for Injection BP (5000 IU & 2ml Ampoule of Sodium Chloride Injection BP (0.9% w/v)	Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of valid legalized COPP.

Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 23-04-2026:

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

Following is the recommendation of panel:

Recommendation

Based on the virtual inspection of M/s SHREE VENKATESH INTERNATIONAL LIMITED, Block No. 311, Kosamba Pardi Road, Village: Nandav, Taluka: Mangrol, Dist. Surat – 394125, Gujarat- INDIA, documents reviewed, interview of the management and technical personnel conducted, panel of inspectors is of the view, **not to recommend registration of below mentioned product based on the non-availability of the approval of biological section of the manufacturer by Regulatory Body of Country of origin.**

Ovigil GP 5000IU

2ml Vial of Chorionic Gonadotrophin for Injection BP (5000 IU & 2ml Ampoule of Sodium Chloride Injection BP (0.9% w/v)

Decision of 360th meeting:

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

In the light of above decision, a personnel hearing letter was issued to M/s Aspire Life Sciences (Private) Limited, Jhelum.

Proceedings of 361st meeting:

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

1. Mr. Sufyan Ashraf, CEO

2. Mr. Irfan Shabbir, Director Marketing

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

Decision of 361st Meeting:

After due deliberation, the Registration Board decided to reject the registration application(s) for the above-mentioned product manufactured by M/s Shree Venkatesh International Limited, Block No. 311, Kosamba Pardi Road, Village Nandav, Taluka Mangrol, District Surat – 394125, Gujarat, India,

due to non-availability of the approval of biological section of the manufacturer by Regulatory Body of Country of origin.

Case No. 09: Virtual Inspection of Manufacturer Abroad for Biological product applied by M/s PharmEvo Private Limited Karachi approved in 353rd meeting of Registration Board.

Following product of M/s PharmEvo Private Limited Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi was approved in 353rd meeting of Registration Board as per following details:

Name of Manufacturer	Brand Name & Composition
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.	**Pembro Injection 100mg/4ml** One vial of 4 mL contains: Pembrolizumab.....100mg

Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 23-04-2026:

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

Following is the recommendation of panel:

Conclusion

Based on the virtual inspection of 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, documents reviewed, interview of the management and technical personnel conducted, the panel of inspectors concludes that the grant of registration for the below-mentioned biological product is **not recommended** due to the following observations:

Pembro Injection 100mg/4ml
One vial of 4 mL contains:
Pembrolizumab.....100mg

I. **Dedicated and self-contained facilities for the manufacture of biological products were not available. Pharmaceutical and biological products, including COVID-19 vaccines (at the time of outbreak), manufactured in common areas on a campaign basis.**
II. **The submitted product development data and drug product dossier indicated that manufacturing activities were performed by JSC "BIOCAD" rather than M/s Limited Liability Company "PK-137".**

Decision of 360th meeting:

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

In the light of above decision, a personnel hearing letter was issued to M/s **PharmEvo Private Limited Karachi.**

Proceedings of 361st meeting:

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

1. Mr. Imran Panawala

2. Mr. Sunny Pervaiz

3. Mr. Shahryar Khalid

4. Mr. Nadeem Rehmat

5. Ms. Nikita

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

Decision of 361st meeting:

The Registration Board noted that there is a significant therapeutic need for Pembrolizumab, a programmed death receptor-1 (PD-1) inhibitor with an established clinical role in the management of a broad range of malignancies. Its clinical applications include, inter alia, melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, urothelial carcinoma, renal cell carcinoma, colorectal cancer with specific molecular characteristics, gastric and gastroesophageal cancers, cervical cancer, endometrial cancer, and other selected malignancies. The availability of Pembrolizumab is therefore considered to be of considerable clinical importance.

In view of the substantial disease burden associated with these malignancies and the established clinical utility of Pembrolizumab in appropriately selected patients, the Board considered that the continued availability of the product may contribute to addressing an important unmet therapeutic need and facilitate patient access to an established treatment option for cancer. Furthermore, in consideration of the approval of the product by ANMAT, Argentina, the application may be processed further in accordance with the applicable regulatory requirements, subject to satisfactory assessment of the submitted quality, safety, efficacy, and Good Manufacturing Practices (GMP)-related evidence.

In view of the above, the Registration Board decided that a product-specific inspection of the overseas manufacturing facility shall be conducted to verify compliance with applicable GMP requirements and to verify the submitted data. The matter regarding the grant of Marketing Authorization (MA) shall be considered subsequently upon satisfactory confirmation of GMP compliance, along with a comprehensive evaluation and verification of the submitted technical and scientific data. The final regulatory decision shall be based on the totality of the available evidence, including the outcome of the product-specific inspection and the adequacy of the submitted quality, non-clinical, and clinical data, as well as any other information considered relevant to establishing the overall benefit-risk profile of the product.

Product specific inspection, shall be conducted by following panel of experts:

i. **Two evaluators from Division of Biological Evaluation & Research, DRAP.**
ii. **Dr. Ali Jan, Director Drug Testing Laboratory, Quetta.**
iii. **Mr. Syed Adnan Rizvi, Director Drug Testing Laboratory, Karachi.**
iv. **Mr. Asad Abrar, Director Drug Testing Laboratory, Bahawalpur.**

Case No. 10: **Imported human biological applied by M/s Medi Mark Pharmaceuticals deferred in 350th meeting:**	
Name, address of Applicant / Importer	M/s **Medi Mark Pharmaceuticals** 588/B-I ,Karbala Road ,Liaquat Chowk , Sahiwal.
Details of Drug Sale License of importer	**License No:** 02-367-0154-049333D 588/B-I ,Karbala Road ,Liaquat Chowk , Sahiwal. **Valid Upto:** 20-12-2028
Name and address of marketing	**M/S** Sichuan Yuanda Shuyang Pharmaceiticals Co.,LTd 1- No. 888, 5th Antai Road, High-tech Zone, Chengdu, 611730, Sichuan, China.

authorization holder (abroad)	2- JieErNian,Zhonghe, Hi-Tech zone , Chengdu , P.R.C,China.
Name, address of manufacturer(s)	**M/s** Sichuan Yuanda Shuyang Pharmaceiticals Co.,LTd 1- No. 888, 5th Antai Road, High-tech Zone, Chengdu, 611730, Sichuan, China. 2- JieErNian,Zhonghe, Hi-Tech zone , Chengdu , P.R.C,China.
Name of exporting country	China
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original legalized CoPP certificate No.Sichuan 20220079 dated 23-09-2022 issued by **Sichuan Medical Products Administration No.98 ,Yu Sha Road ,Chengdu ,Sichuan Province, China**. The certificate was valid till 17-08-2024.
Details of letter of authorization / sole agency agreement	Firm has submitted Original legalized letter of authorization from **Sichuan Yuanda Shuyang Pharmaceiticals Co.,Ltd 888, 5th Antai Road, High- tech Zone, Chengdu, 611730, Sichuan, China** in favour of Medi Mark Pharmaceuticals Liaquat Chowk ,Sahiwal , Pakistan, as their sole distributor for applied product. The LOA is issued on 11-10-2022 which is valid for 05 years.
Status of the applicant	Importer
Status of application	Generic Drug Product (GDP)
Intended use of pharmaceutical product	Domestic sale
For imported products, specify one the these	Finished Pharmaceutical product import
Dy. No. and date of submission	R & I Dy. No. 676, Date Jan 09,2023
Details of fee submitted	Challan No.067101816592 Amount: 150,000 Date of submission: 03-01-2023
The proposed proprietary name / brand name	**Medigam Inj 2.5gm**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Human Immunoglobulin 2.5gm/vial , I.V (5% ,50ml)
Pharmaceutical form of applied drug	Liquid Injection I.V
Pharmacotherapeutic Group of (API)	Immunoglobulins /Immune sera
Reference to Finished product specifications	In House Chinese Pharmacopoeia but More stringent than U.S.P /B.P
Proposed Pack size	1,s vial & 1 x 10,s
Proposed unit price	As Per SRO + CPI
The status in reference regulatory authorities	Intraglobin Inj. (Nabiqasim) Mnf. by Biotest Pharma Germany , Germany
For generic drugs (me-too status)	Intraglobin Inj. (Nabiqasim) Mnf. by Biotest Pharma Germany , Germany
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification

		of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/S Sichuan Yuanda Shuyang Pharmaceiticals Co.,LTd 1-No. 888, 5th Antai Road, High-tech Zone, Chengdu, 611730, Sichuan, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated stability. The accelerated stability study data is conducted at 25°C ± 2°C up to 6 months & long term Stability data for three batches conducted at 5°C ± 3°C for the period of 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence and Comparative Dissolution Profile
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Injection vial made of neutral borosilicate glass closed with halogenated butyl rubber SP8-06. The rubber stoppers are sealed with aluminium plastic cap (Polypropylene) Attachment 3.2.P.7
	Stability study data of drug product, shelf life and storage conditions	The accelerated stability study data is conducted at 25°C ± 2°C / 60% RH ± 5% RH up to 6 months. The long Term stability study data is conducted at 5°C ± 3°C up to 36 months. 36 Month 2 C to 8 C
	Decision of 344th RB 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, carcinogeneicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies: **ii.** Documented and published clinical studies, biosimilarity studies including In-vitro, In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication: **iii.** Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product: **iv.** Post-marketing surveillance (Pharmacovigilance) study reports.

Evaluation by BE&R:

The firm has submitted a reply and provided following:

1. **In clinical part, the manufacturer has submitted clinical trial protocol and justification of not performing clinical trials earlier as below;**

Our company's Human Immunoglobulin (pH4) for Intravenous Injection (Hereinafter referred to as IVIG) was first registered and marketed in 1998. This product is derived and purified from healthy human plasma using the internationally recognized low temperature ethanol protein fractionation method. As an endogenous substance of the human body, it offers high safety, minimal side effects, and undergoes multi-stage safety screening throughout its lifecycle, including donor screening, plasma collection, plasma testing, quarantine management, production (including two steps of virus inactivation /removal), product testing and batch release.

At the time of initial registration, due to the confirmed indications and efficacy of IVIG, the Chinese drug regulatory authority did not require the company to conduct clinical trials for registration. Therefore, no clinical trial data was included in the registration dossier for our IVIG product.

Since its first registration, our IVIG has been produced and sold for over 25 years and remains in high demand, the current annual sales reach more than one million vials (Equivalent to 5g/vial). Long-term stability data has shown consistently stable product quality, and extensive clinical use over the years has confirmed the product's proven efficacy, high safety, and minimal adverse reactions.

However, to meet the requirements of Pakistan registration regulations, we are willing to conduct additional clinical trials to obtain the necessary clinical data.

We hereby certify that we are conducting clinical trials in Brazil for Human Immunoglobulin (pH4) for intravenous injection, targeting the indication of Primary Immunodeficiency Disease (PID). Additionally, we plan to conduct clinical trials for the same product, focusing on the indication of Idiopathic Thrombocytopenic Purpura (ITP) in Turkey. All clinical trials are expected to be completed in early 2027. Upon completion, the relevant documents will be submitted. Detailed clinical trial protocols are provided in Attachment 1 and Attachment 2.

Name: Gan Ke, Regulatory Manager

Date: February 14, 2026

Attachment 1: Clinical trial protocol for IVIG for the indication of PID.

Attachment 2: Clinical trial protocol for IVIG for the indication of ITP (Draft).

2. In non-clinical part, the firm has submitted test report of
   - "**Vascular Irritation test of single or multiple intravenous Injections of Human Immunoglobulin (pH4) for Intravenous Injection in Japanese White Rabbits."**

"In-vitro Hemolysis test of Human Immunoglobulin (pH4) for Intravenous Injection."

Decision of 350th meeting of RB:

The Registration Board deferred the case for submission of complete non-clinical (safety) and clinical (efficacy) data.

Evaluation by BE&R:
Firm has submitted following;

- **Post-Marketing Surveillance data (PSURs) covering two consecutive 5-year periods — 18 December 2012 to 17 December 2017, and 18 December 2017 to 17 December 2022 — representing 10 years of accumulated post-marketing safety experience.**
- **Clinical trial approvals, approved study protocols, and status update from two ongoing pivotal clinical studies: the PID clinical study currently underway in Brazil (registry reference NCT06089122), and the ITP clinical study currently underway in Türkiye (registry reference NCT07233213).**
- **Interim pharmacokinetic (PK) analysis report from the Brazil PID study, showing the expected rise in total IgG concentration following repeated infusion, an IgG subclass profile consistent with the expected characteristics of the product, and supportive antibody responses (including anti-pneumococcal polysaccharide, anti-Haemophilus influenzae, and anti-measles antibodies) confirming the expected systemic exposure and antibody profile in PID patients.**
- **Supportive published literature specifically addressing the use of the product in pericarditis, comprising an observational study on its use in comprehensive pericarditis treatment and an evaluation of its efficacy in overcoming dependence on interleukin-1 inhibitors in chronic and recurrent pericarditis.**
- **A formal declaration from the manufacturer explaining the regulatory and scientific basis for the non-clinical study package submitted for this product.**

We respectfully submit that this package, taken together, represents a substantive and scientifically robust body of evidence bearing directly on the safety, efficacy, and quality profile of the product.

<u>Basis for Requesting Continuation of Evaluation on Submitted Data</u>

We would like to respectfully bring the following points to your kind attention in support of our request that the evaluation of this application proceed on the basis of the data already submitted:

1. **Established Product Class: Human Normal Immunoglobulin (IVIG) is a well-characterized, decades-old plasma-derived therapeutic class with an extensive global safety record and a recognized WHO reference monograph. The core safety and quality expectations for this class are well established in international literature and pharmacopoeial standards.**
2. **Scientific Basis for the Non-Clinical Study Package: As explained in the manufacturer's formal declaration (enclosed), standard toxicological and pharmacological studies are not generally required for the marketing approval of plasma-derived products of this nature, given that their active component — immunoglobulin derived from normal human blood — is a well-characterized human protein rather than a novel chemical or biological entity. Regulatory practice for this product class instead focuses on formulation-specific safety testing, namely local irritancy, hemolysis, and allergenicity, to account for differences in excipients and manufacturing process between products. The manufacturer has completed the applicable formulation-specific tests, namely hemolysis and vascular irritancy tolerance. We would further draw attention to the scientific basis for the limited relevance of animal allergenicity testing for this product class: human blood-derived components are inherently xenogeneic proteins to laboratory animals, such that positive or negative results in animal allergenicity models do not carry meaningful clinical predictive value for human patients. This, together with the product's 25-plus year global marketing history, well-established pharmacological and toxicological profile, verified excipient safety, and consistently favourable post-marketing safety feedback, provides a sound scientific basis for the non-clinical data package submitted.**
3. **Reference Country Approval — Türkiye: The product has been granted registration by the Ministry of Health, Türkiye — a PIC/S member authority and a WHO-recognized reference regulatory body — on the basis of the same data and documentation now before your office. This approval reflects an independent regulatory assessment by a stringent authority and, consistent with WHO's collaborative reliance framework, is submitted as strong corroborating evidence of the product's acceptability.**
4. **Active, Ongoing Clinical Development: The PID study in Brazil (NCT06089122) and the ITP study in Türkiye (NCT07233213) are actively approved and progressing, further reinforcing the clinical evidence base for this product. The interim PK results from the Brazil study — showing an expected rise in total IgG following infusion and antibody responses consistent with the**

product's expected profile — provide additional supportive evidence for the indications applied for.

5. **Post-Marketing Safety Data as Corroborating Evidence: The submitted PSURs, spanning ten years of accumulated post-marketing experience (2012–2022), reflect actual clinical use of the product in patients and, for an established biological product class such as this, provide safety evidence that meaningfully complements the pre-marketing dataset.**
6. **Sufficiency of Evidence for Approval: Taken together — the established safety profile of this product class, the scientific basis for the non-clinical package, the independent Türkiye reference-country approval, ten years of post-marketing safety data, and the supportive interim clinical evidence from the ongoing PID and ITP studies — we respectfully submit that the evidence on record is comprehensive and sufficient to support a favourable benefit/risk determination for this product.**

Decision of 361st meeting:
Registration Board decided to defer the case till submission of Clinical trial data of applied product.

Case No. 11: Application for permission to separately import diluent for veterinary vaccines applied by M/s Vety-Care.

M/s Vety-Care submitted that previously the diluent for veterinary vaccines was being imported separately and the manufacturer also exports it as a separate product. Due to DRAP Policy change, we were asked to apply for combo pack. We then applied for Diluent Addition with Vaccine (Tracking – XE4-QTV-GUZD). Application was approved and letter was issued. As the Manufacturer produces the diluent as a separate product & Both Vaccines and Diluent have different storage conditions.

Vaccine – 2oC - 8oC & Diluent < 25oC

We hereby request to issue permission for

Separate import with separate invoice. As this Diluent is used in multiple vaccines it is not possible to mention different registration numbers in one Diluent therefore issue addendum letter with Diluent Registration number mentioned.

The matter was discussed in 12th meeting of Expert Working Group (EWG) for Veterinary Drugs wherein it was recommended that separate diluent for veterinary vaccines may be registered but only with following conditions:

i. The diluent shall be manufactured by the same manufacturer which is manufacturing the vaccine and additionally for imported products, the applicant shall submit valid evidence of availability of proposed diluent with vaccine in country of origin.
ii. The registration letter of diluent may be issued with the names of veterinary vaccines for which diluent is required.

Decision:

Keeping in view recommendations of EWG; Registration Board decided to consider applications for grant of registrations to separate diluents for veterinary vaccines but only with following conditions:

i. **The applicant shall submit valid evidence of availability of proposed diluent with vaccine in country of origin.**
ii. **The registration letter of diluent shall be issued separately. However, the names of all veterinary vaccines alongwith Registration Number for which diluent is used shall be mentioned on the letter.**

Meeting ended with a vote of thanks to and from the Chair.

-------End of Document------

Item No. V Additional / Supplementary Minutes

RRR Section

Case No.01: M/s. Weather Folds Pharmaceuticals Plot No. 62/2 Phase-II Industrial Estate Hattar.

1.	Brand Name + Dosage Form and Strength	Resile Syrup
	Composition	Each 5ml Contains: Lactulose……..……3.35gm (Product complies Innovator's Specs)
	Tracking ID and fee details	Challan No. 6223778925 Rs. 97,200/- Challan No.274663810925 Rs. 216,300/- Tracking ID: **D1S-6ZJ-L7NT** Fee for change of source of bulk: Challan No. 223579734 Rs. 156,750/-
	Source of Bulk Lactulose:	M/s. Syngars Technology Co., Ltd. Baishe Industrial Functional Area, Lanxi, Zhejiang, 321116. China.
	Type of form	Oral Solution
	Finished product specifications	USP
	Pack size and Demand Price	120ml, As per SRO
	GMP Status	GMP inspection report dated:17.10.2023 compliance good manufacturer practice.
	RRA status	MHRA Approved
	Remarks:	Resile Syrup (0056343) declared invalid due to non-submission of renewal application in prescribe time period.
	Contract Manufacturer:	M/s. Dyson Research Laboratories (Pvt). Ltd.28-Km Ferozepur Road Lahore
	Manufacturer GMP Status:	GMP certificate based on inspection dated 04th Sep, 2025 by Zhejiang Medical Product Administration (confirmation No. ZJ250274)**.**
	Remarks	The source initially approved as **Fresenius Kabi Austria Gmbh, Estermanntrabe 17/A-4020 linz Austria** (as per registration certificate). Now firm is applying for another source as **M/s. Syngars Technology Co., Ltd. Baishe Industrial Functional Area, Lanxi, Zhejiang, 321116. China** . The reasons provided are as under: ***The Fresenius Kabi Austria is not anymore existing; hence we opted for change of Source.***
	Decision: The Board deferred above cases and directed the firm either to submit data of: 1. Development of 03 trial batches of the applied product. 2. Stability studies including accelerated and real time till 3rd month time point. 3. Pharmaceutical equivalence studies against reference/innovator's/comparator's product by performing all the quality tests. 4. Comparative dissolution profile against reference/innovator's/comparator's (where applicable). 5. Analytical method of drug product and its verification/validation. Or 1. Testing method and record.	

	2. Long term stability testing upto the shelf life.

I&V Section

1	Name and address of manufacturer/ Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Doxlina 50% Water Soluble Powder
	Composition	Each kg contains: Neomycin Sulphate…500gm
	Diary No. Date of R & I & fee	Dy. No. 11671; 06.03.2019 PKR. 20,000/-; 05.03.2019
	Pharmacological Group	Other aminoglycosides
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 2.5kg; decontrolled
	Me-too status	XEDO-50 POWDER. Reg. No. 80141
	GMP status	The firm was inspected on 30.06.2021 wherein GMP status was rated satisfactory.
	Remarks of the Evaluator	
	Previous decision (M-307)	Deferred for consideration on its turn and updated GMP status of the firm from QA & LT division.
	Evaluation by PEC	Updated inspection report submitted. The firm submitted that there is typo mistake in the label claim and the dossier is meant for doxycycline HCl. The firm submitted photocopy of the original dossier, where the API is Neomycin Sulphate.
	Decision: (M-316) Deferred for submission of following: **Revised Form 5 along with correct master formula.** • **Submission of fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of drug substance), as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.and Rs. 30,000/- fee** **Firm has submitted revised form 5 along with fee as per SRO.** Rs.38,700/-Deposit slip No. 251625703 Each kg contains:- Doxycycline HCl 500gm Submitted for consideration of the Board **Decision: Approved. The firm shall submit fee Rs. 9400/- in pre-registration variation for specification correction before issuance of registration letter.**	
2.	Name and address of Applicant	M/s Chakwal Pharma International, OTI Plaza, Basement Ground, 1st ,2nd & 3rd floor, 210 Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, Lahore
	Detail of Drug Sale License	Address: OTI Plaza, Basement Ground, 1st ,2nd & 3rd floor, 210 Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, Lahore Validity: 13/11/2028 Status: License to sell drugs as a Distributor (Form No. 11)
	Name and address of manufacturer	M/S. Alfasan International B.V., Kuipersweg 9, 3449 JA Woerden The Netherland

	Name and address of marketing authorization holder	M/S. Alfasan Netherland B.V. Kuipersweg 9, 3449 JA Woerden The Netherland
	Name of exporting country	The Netherland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 18514 Dated 24-07-2023
	Fee including differential fee	Rs : 150,000 Dated 12-07-2023(Slip No. 48778211280)
	Brand Name +Dosage Form + Strength	Ketamine 10% Solution for Injection
	Composition	Each ml Contains: **Ketamine as HCl**…100mg
	Finished Product Specification	As per innovator's specifications
	Pharmacological Group	Anaesthetics
	Shelf life	4 years
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	Ketexx 100 mg/ml solution for injection (**Approved in Netherlands**)
	Me-too status	Not registered with DRAP
	Detail of certificates attached	➢ Original legalized COPP BD/2022/No. of Certificate 257951 dated 04-08-2022 certified by Medicines Evaluation Board Agency- Veterinary Medicinal Products Unit, Ministry of Economic Affairs, The Netherlands confirms the free sale status in exporting country as well as GMP status of the manufacturer ➢ Original legalized letter of exclusive sole distributor/ authorization dated: 05-05-2017
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 48-month real time stability studies data of three batches at zone IV-A conditions. **Target species:** Dogs, cats, horses, cattle, sheep, goats, laboratory animals • Ketamine and its salts have been declared as **"Psychotropic"** vide SRO No. 1350(I)/2021 dated 15-10-2021.
	Decision: (M-339) Deferred for the submission of NOC from the Narcotic Control Division / relevant controlling authority. **Firm Reply:** Firm has submitted copy of NOC issued from Ministry of Interior and Narcotics Control, Islamabad vide letter No.15-120/2025-CS dated 07th July, 2026. Submitted for consideration of the Board **Decision:-Approved as per current import policy for inspection of manufacturer abroad. The firm shall submit original legalized CoPP/FSC+GMP certificate before issuance of registration letter.**	

Case No.01. Suspension of Registration of Allay-D Tablet 75/25mg Registered in Favor of M/s Tabros Pharma (Pvt) Ltd. Karachi

Registration Board in its 354th meeting (held on 04th-5th March, 2022) approved the registration application of 'Allay-D (Tramadol + Dexketoprofen) Tablet 75/25mg' in favor of M/s Tabros Pharma (Pvt) Ltd., Plot No. L-20/B, Sector 22, F.B. Industrial Area, Karachi by way of contract manufacturing at M/s Wimits Pharmaceutical (Pvt.) Ltd., Plot # 129, Sundar Industrial Estate Raiwind Road, Lahore. As per minutes of meeting, the case was cross referred with already approved registration of M/s Wimits, Lahore. Accordingly, **registration letter was issued on 06.05.2026**.

However, it has been identified that the **cross referred application of M/s Wimits was conditionally approved in 351st meeting** subject to verification of authenticity of submitted stability data by panel constituted by Chairman Registration Board and **till to date the inspection has not been conducted**.

Foregoing in view, M/s Tabros, Karachi has **voluntarily withdrawn/ surrendered** the registration letter of 'Allay-D Tablet 75/25mg' till the product specific inspection is concluded.

Accordingly, instant case has been placed before the Registration Board for **Suspension of registration of 'Allay-D Tablet 75/25mg; Reg.No.134893'** till the verification of authenticity of submitted stability data by the panel. In this context, a **panel has already been constituted** and communicated to the panel members vide letter dated 06.08.2026.

Decision: **Registration Board suspended the registration of "Allay-D Tablet 75/25mg; Reg. No.134893; 62B-8R9-AMZM" till the product specific inspection of M/s Wimit Pharmaceutical (Pvt.) Ltd., Lahore is concluded.**

Furthermore, with respect to cross referred applications, the Board decided that it shall be mandatory for the applicant to attach Registration Certificate/ PRV Approval letter of the cross referred product which is already approved by the relevant forum.

Case No.02. Approval for Registration of 2SUM 1.5g Injection IV/IM in Favor of M/s Healthtek Pvt. Ltd., Karachi.

The case was present in the hard agenda and has now been included in the E-App.

Case No.03. Conditionally Approved Registration Applications of M/s City Pharmaceutical Laboratories, Karachi

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

S/N	Product Detail	Dy. No. & Date of Application	Decision of 316th Meeting of RB/ Remarks of Reg-I Section (if any)
1.	Claronil 500mg Tablet Clarithromycin…..500mg/tab USP	**Dy.No 10793 dated 05-03-2019**	**Approved with following label claim: Each Film Coated Tablet Contains: Clarithromycin……..…500mg Registration Board further decided that registration letter will be issued after**

			submission of Undertaking at the end of form 5. **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from un-coated tablet to film coated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** In line with the decision of RB, the firm has submitted fee of Rs. 7500/-(S#4929712164 dated 27.10.2023) **without undertaking.**
2.	Amoxi 500mg IV Injection Each Vial contains: Amoxicillin Sodium sterile powder for solution for injection eq. to Amoxicillin … 500mg BP	**Dy. No. 32568-dated 13-12-2021**	**Approved with BP specification.** • **Manufacturer will place first three commercial batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three commercial batches as per the commitment submitted in the registration application.** • **Firm shall submit following before issuance of registration letter:** ➢ **Performance of accuracy parameter in the analytical method verification studies of drug substance.** **Compatibility studies of finished product with diluent.**
3.	Asrovit 20mg Tablet Atorvastatin Calcium……..…20mg/tab USP	**Dy.No 10791 dated 05-03-2019**	**Approved with following label claim:** **Each Film Coated Tablet Contains:** **Atorvastatin as calcium trihydrate…….20mg** **Registration Board further decided that registration letter will be issued after submission of:** **Revised master formulation adjusting the weight of API considering the salt factor** **Undertaking the end of Form 5** **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt factor of the drug substance) and change of formulation from un-coated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
4.	Asrovit 10mg Tablet Atorvastatin Calcium……..10mg/tab USP	**Dy.No 10790 dated 05-03-2019**	**Approved with following label claim:** **Each Film Coated Tablet Contains:** **Atorvastatin as calcium trihydrate…….10mg** **Registration Board futher decided that registration letter will be issued after submission of:** **Revised master formulation adjusting the weight of API considering the salt factor**

			Undertaking at the end of form 5 **Firm shall submit fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt factor of the drug substance) and change of formulation from un-coated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
5.	Ibistan DS 300/25mg Tablet Each Tablet Contains: Irbesartan…….300mg Hydrochlorothiazide...25mg USP	**Dy.No 10789 dated 05-03-2019**	**Approved with following label claim:** **Each Film Coated Tablet Contains:** **Irbesartan…….300mg** **Hydrochlorothiazide…….25mg** **Registration Board futher decided that registration letter will be issued after submission of Undertaking at the end of form 5.** **Firm shall submit fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from un-coated tablet to film coated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
6.	Ibistan 150/12.5mg Tablet Each Tablet Contains: Irbesartan……150mg Hydrochlorothiazide.12.5mg USP	**Dy.No 10788 dated 05-03-2019**	**Approved with following label claim:** **Each Film Coated Tablet Contains:** **Irbesartan…….150mg** **Hydrochlorothiazide…...12.5mg** **Registration Board further decided that registration letter will be issued after submission of Undertaking at the end of form 5** **Firm shall submit fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from un-coated tablet to film coated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
7.	Ibistan plus 300/12.5mg Tablet Each Tablet Contains: Irbesartan……..…300mg Hydrochlorothiazide..12.5mg USP	**Dy.No 10792 dated 05-03-2019**	**Approved with following label claim:** **Each Film Coated Tablet Contains:** **Irbesartan…….300mg** **Hydrochlorothiazide…...12.5mg** **Registration Board further decided that registration letter will be issued after submission of Undertaking at the end of form 5.** **Firm shall submit fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from un-coated tablet to film coated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
8.	Peridoline DS Tablet 8/10mg Each Tablet Contains: Perindopril……8mg Amlodipine (as Besylate)...……10mg	**Dy.No 10795 dated 05-03-2019**	**Approved with innovator's specifications and following label claim:** **Each Film Coated Tablet Contains:** **Perindopril Erbumine……..8mg** **Amlodipine (as Besylate)……..10mg**

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

Proceedings of 358th Meeting:

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

Decision of 358th Meeting:

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

In compliance with the above-mentioned decision, M/s City Pharmaceutical Laboratories, Karachi was issued final reminder in hard copy on 30.06.2026 and via e-App TID PJ9-E4D-J9HX on 02.07.2026. However, the applicant has not replied till to date.

Decision: **Keeping in view that the applicant has not submitted the requisite information/ documents/ fee despite of multiple reminders issued by PE&R Division, Registration Board rejected the registration applications of following products which were conditionally approved by the Board in its 316th meeting.**

S/N	Product Detail	Dy. No. & Date of Application
1.	Claronil 500mg Tablet Clarithromycin…..500mg/tab USP	Dy.No 10793 dated 05-03-2019
2.	Amoxi 500mg IV Injection Each Vial contains: Amoxicillin Sodium sterile powder for solution for injection eq. to Amoxicillin … 500mg BP	Dy. No. 32568- dated 13-12-2021
3.	Asrovit 20mg Tablet Atorvastatin Calcium……..…20mg/tab USP	Dy.No 10791 dated 05-03-2019
4.	Asrovit 10mg Tablet Atorvastatin Calcium……..10mg/tab USP	Dy.No 10790 dated 05-03-2019
5.	Ibistan DS 300/25mg Tablet Each Tablet Contains: Irbesartan…….300mg Hydrochlorothiazide...25mg USP	Dy.No 10789 dated 05-03-2019
6.	Ibistan 150/12.5mg Tablet Each Tablet Contains: Irbesartan…….150mg Hydrochlorothiazide.12.5mg USP	Dy.No 10788 dated 05-03-2019
7.	Ibistan plus 300/12.5mg Tablet Each Tablet Contains: Irbesartan…….….300mg Hydrochlorothiazide..12.5mg USP	Dy.No 10792 dated 05-03-2019
8.	Peridoline DS Tablet 8/10mg Each Tablet Contains: Perindopril……8mg Amlodipine (as Besylate)...……10mg Manufacturer's specifications	Dy.No 10795 dated 05-03-2019
9.	Peridoline plus Tablet 4/10mg Each Tablet Contains: Perindopril……..…4mg Amlodipine (as Besylate)..……...10mg Manufacturer's specifications	Dy.No 10796 dated 05-03-2019

10.	**Peridoline Tablet 4/5mg** **Each Tablet Contains:** **Perindopril…….4mg** **Amlodipine (as Besylate)..……5mg** **Manufacturer's specifications**	**Dy.No 10794 dated 05-03-2019**

Case No.04. Manufacturing Requirements for Aztreonam Containing Products

In compliance with the decision taken by the Registration Board in its 357th meeting (held on 21st April, 2026), M/s Genix Pharma Pvt Ltd., Plot No. 44-45-B, Korangi Creak Road, Karachi was issued registration of "Aztreo (Aztreonam) Injection 2g; Reg.No.135076".

Furthermore, as per available record, M/s Genix, Karachi is the first company which has been issued registration of 'Aztreonam Injection 2g' for **local manufacturing** under '**Dry Powder Injection (Penem) Section**'.

'Aztreonam' falls under the class "Monobactams" which are ***Non-Penicillin Beta-Lactam Antibacterial Drugs***.

Beta-lactam antibacterial drugs, including penicillin and the non-penicillin classes, share a basic chemical structure known as the beta-lactam ring. The side chain associated with the beta-lactam ring is a variable group that contributes to antibacterial activity.

The beta-lactam ring and side chains are also responsible for the allergenic properties of beta-lactam antibacterial drugs. These structures can induce the formation of antigenic determinants that lead to the production of specific immunoglobulin E (IgE) antibodies that can induce Type 1 hypersensitivity (allergic) reactions in susceptible individuals.

As per draft guidance published by USFDA in June-2022 for prevention of cross-contamination https://www.fda.gov/regulatory-information/search-fda-guidance-documents/non-penicillin-beta-lactam-drugs-cgmp-framework-preventing-cross-contamination-0:

Beta-lactam antibacterial drugs display properties of cross-reactivity, in which the secondary exposure need not be to the same compound. For example, patients with a history of hypersensitivity to penicillin, may also experience an IgE-mediated reaction to a drug in another class, such as cephalosporins, penems and monobatcams.

Regardless of the rate of cross-reactivity among beta-lactam antibacterial drugs or the mechanism of action by which such cross-reactivity may occur, a potential health risk to patients (i.e., life-threatening anaphylaxis) can result from cross-contamination among all classes of drugs and compounds containing a beta-lactam ring.

Therefore, manufacturers should manage the risk of cross-contamination throughout the products' life cycles and risk management strategies should include stringent controls to prevent cross-contamination.

The manufacturing operations of any class of non-penicillin beta-lactam antibacterial drugs should be completely and comprehensively separated from areas in which any other drugs for human use are manufactured, including any other class of beta-lactam antibiotics. *This separation includes independent air handling systems.*

Manufacturing operations that are restricted solely to products ***within a specific class of non-penicillin beta-lactam antibacterial drugs*** *(e.g., cephalosporins) generally would not mandate separate facilities and air handling systems for each of those products;* ***production campaigning in the same facility and appropriate cleaning (including qualification to demonstrate removal of beta-lactams) after each campaign may be sufficient to prevent cross-contamination***.

Keeping in view the above recommendations, the case has been placed before the Board for consideration of following proposals:

a. To facilitate availability of locally manufactured products by allowing production on campaign basis.
b. Recommendations to Licensing Division, DRAP regarding grant of dedicated facility for manufacturing of Monobactams (e.g., Aztreonam) to avoid the risk of cross contamination.
c. Out of Queue consideration of any application applied for registration of 'Monobactams' to be manufactured at dedicated facility newly approved by the Licensing Division, DRAP.

Decision: **Registration Board noted that there are only 2 products registered for finished import of 'Aztreonam Injection" and M/s Genix, Karachi is the first company which has been granted registration for local manufacturing of the said product.**

Therefore, in order to ensure the availability of self-manufactured products and to avoid the risk of cross contamination, the board deliberated that there is a need to gradually upgrade the manufacturing requirement to dedicated facility for "Aztreonam (i.e., Monobatam- Non penicillin Beta lactam Antibacterials).

Foregoing in view, the Board decided as under:

a. M/s Genix, Karachi shall be issued directions regarding manufacturing of 'Aztreonam Injection 2g' in 'Penem Section' on campaign basis only under intimation to the relevant FID before every change.
b. To avoid the risk of cross contamination and cross reactivity associated with manufacturing of different classes of 'Beta Lactam Antibacterial Drugs' in single dedicated facility, recommendations shall be forwarded to Licensing Division, DRAP regarding grant of dedicated facility for manufacturing of 'Monobactams (e.g., Aztreonam)'.
c. Any application received for registration of 'Monobactams' to be manufactured at dedicated facility newly approved by the Licensing Division, DRAP shall be considered 'Out of Queue' by the Registration Board. After approval of dedicated facility for Monobactams by Licensing Division, permissions for campaign manufacturing shall either be revoked or shifted to contract manufacturing.

Case No.05. Correction in Minutes of 359th Meeting of Registration Board.

Registration Board in its 358th meeting (held on 12th May, 2026) considered following registration applications of M/s Hiranis Pharmaceuticals Pvt. Ltd., E-145-149, North Western Industrial Zone, Port Qasim, Karachi:

S/N	Product Detail	e-App TID	Decision of 358th Meeting
1.	Eslicar 800mg Tablet Each tablet contains: Eslicarbazepine Acetate.....800mg	B7J-W18-2B8Q	Not Applicable
2.	Eslicar 600mg Tablet Each tablet contains: Eslicarbazepine Acetate.....600mg	DJ6-EG3-TUM1	Not Applicable
3.	Eslicar 400mg Tablet Each tablet contains: Eslicarbazepine Acetate.....400mg	MTR-XE5-TZX	Not Applicable
4.	Eslicar 200mg Tablet Each tablet contains: Eslicarbazepine Acetate.....200mg	T8L-AH3-Y3GZ	Not Applicable

5.	Safcort Oral Suspension Each ml contains:- Deflazacort.....22.75mg	XEP-EZW-AQSH	Not Applicable
6.	Safcort 30mg Tablet Each tablet contains:- Deflazacort.....30mg	TBU-ABX-5TDH	Not Applicable
7.	Safcort 18mg Tablet Each tablet contains:- Deflazacort.....18mg	MU4-61V-4ZYQ	Not Applicable
8.	Safcort 36mg Tablet Each tablet contains:- Deflazacort.....36mg	494-TL5-XDNL	Not Applicable
9.	Safcort 6mg Tablet Each tablet contains:- Deflazacort.....6mg	3G1-WDD-J8QZ	Not Applicable
10.	Rinvok 45mg Tablet Each film coated prolonged release tablet contains: Upadacitinib Hemihydrate eq. to Upadacitinib 45mg	3UL-Y8N-G7JN	Not Applicable
11.	Rinvok Oral Solution Each ml contains: Upadacitinib Hemihydrate Eq.to Upadacitinib.....1mg	8HA-N8D-S5SR	Not Applicable
12.	Rinvok 30mg Tablet Each film coated prolonged release tablet contains: Upadacitinib Hemihydrate eq. to Upadacitinib 30mg	AB6-5Y6-248N	Not Applicable
13.	Rinvok 7.5mg Tablet Each film coated prolonged release tablet contains: Upadacitinib Hemihydrate eq. to Upadacitinib 7.5mg	WPW-B8A-363E	Not Applicable

The firm initially informed that due to over-occupancy of the available 21 CFR-compliant HPLC systems, the stability testing of the trial batches of above-mentioned products was performed on a GxP-compliant HPLC system.

However, the firm submitted the required data (including audit trail report/ system log) after the 358th meeting.

Accordingly, the cases were with-held and decision was recorded as "Not Applicable".

Later on, the above mentioned cases were again presented and approved by the Board in its 359th meeting (held on 09.06.2026). However, under 'evaluation remarks' it was inadvertently stated that the above-mentioned cases were rejected by the Board in its 358th meeting.

Accordingly, the instant case has been placed for correction in previously submitted remarks with respect to above mentioned cases.

Decision: Registration Board noted the information.

1.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 15395 dated 19-06-2023
	Details of fee submitted	Rs.75,000/- dated 07-06-2023
	The proposed proprietary name / brand name	**Ondanz 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule (4ml) Contains: Ondansetron as HCl..... 8mg
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Onset 4mg/2ml Injection by M/s Pharmedic (Pvt) Ltd.
	Proposed Pack size	As per SRO

Evaluation by PEC:

Section#	Observations	Firm's response
1.1	Form 5F has been submitted from the contract manufacturer instead of the contract giver.	
1.5.2	Revised label claim shall be submitted declaring complete salt form of the drug substance along with applicable fee.	
3.2.S.4.3	Drug substance analytical method verification studies shall be submitted from the drug product manufacturer.	
3.2.P.2.2.1	Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product.	
3.2.P.3.3	Flow chart submitted for manufacturing procedure is of Liquid vials whereas applied formulation is in ampoule.	
3.2.P.3.4	Submitted details are for the Phytonadione while the applied formulation is of Ondansetron Injection.	
3.2.P.3.5	• Submitted process validation protocol does not include details of terminal sterilisation. Justification shall be submitted in this regard. • Submitted process validation protocol does not include any details of sampling plan and critical process parameters.	
3.2.P.5.1	Limits for average volume has been declared as 2ml -2.2 ml , whereas the applied formulation is of 4 ml ampoule.	
3.2.P.5.2	Submit drug product analytical procedure from M.s Weather folds instead of submitting USP monograph extract.	

3.2.P.5.4	• Submitted batch analysis COA of stability batches declare average volume of ampoule as 2ml, whereas applied formulation is of 4ml ampoule. • Submitted batch analysis COA of stability batches does not include performance of particulate matter test.	
3.2.P.6	COA of reference/working standard, used for analysis of the drug product stability batches, shall be submitted.	
3.2.P.7	Type of glass for the ampoule shall be submitted.	
3.2.P.8.3	• Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance. • Details of batch size and manufacturing date are different between COAs submitted in section 3.2.P.5.4 and stability sheets in section 3.2.P.8.3 • Submit raw data sheets for stability studies declaring the concentration of sample and standard preparations in Assay test.	

Decision of 339th meeting: Deferred for submission of reply to above cited shortcomings.

Reply by the firm:

The firm has referred the minutes of 343rd meeting of Registration. The applied product manufactured by M/s Weather Folds Pharmaceuticals was approved on Form 5F.

Following are the details of the approved product.

Application form: Form 5F

Diary Number**:** Dy. No. 15396: 19-06-2023

Meeting: 339th

Decision: Approved.

2.	Name, address of Applicant / Marketing Authorization Holder	M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 16610 dated 04-07-2023
	Details of fee submitted	Rs.75,000/- dated 07-06-2023
	The proposed proprietary name / brand name	**Ondanz 4mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains: Ondansetron as HCl…4mg
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Onset 4mg/2ml Injection by M/s Pharmedic (Pvt) Ltd.
	Proposed Pack size	As per SRO

Evaluation by PEC:

Section#	Observations	Firm's response
1.1	Form 5F has been submitted from the contract manufacturer instead of the contract giver.	
1.5.2	Revised label claim shall be submitted declaring complete salt form of the drug substance along with applicable fee.	
1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	
3.2.S.4.3	Drug substance analytical method verification studies shall be submitted from the drug product manufacturer.	
3.2.P.2.2.1	Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product.	
3.2.P.3.3	Flow chart submitted for manufacturing procedure is of Liquid vials whereas applied formulation is in ampoule.	
3.2.P.3.4	Submitted details are for the Phytonadione while the applied formulation is of Ondansetron Injection.	
3.2.P.3.5	• Submitted process validation protocol does not include details of terminal sterilisation. Justification shall be submitted in this regard. • Submitted process validation protocol does not include any details of sampling plan and critical process parameters.	
3.2.P.5.2	Submit drug product analytical procedure from M.s Weather folds instead of submitting USP monograph extract.	
3.2.P.5.4	• Submitted batch analysis COA of stability batches does not include performance of particulate matter test.	
3.2.P.6	COA of reference/working standard, used for analysis of the drug product stability batches, shall be submitted.	
3.2.P.7	Type of glass for the ampoule shall be submitted.	
3.2.P.8.3	• Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance. • Details of batch size and manufacturing date are different between COAs submitted in section 3.2.P.5.4 and stability sheets in section 3.2.P.8.3 • Submit raw data sheets for stability studies declaring the concentration of sample and standard preparations in Assay test.	

Decision of 339th meeting: Deferred for submission of reply to above cited shortcomings.

Reply by the firm:
The firm has referred the minutes of 343rd meeting of Registration. The applied product manufactured by M/s Weather Folds Pharmaceuticals was approved on Form 5F.
Following are the details of the approved product.
Application form: Form 5F
Diary Number: Dy.No 16612 dated 04-07-2023
Meeting: 343rd

Decision: Approved.

3.	Name, address of Applicant / Marketing Authorization Holder	M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 15686 dated 21-06-2023
	Details of fee submitted	Rs.75,000/- dated 07-06-2023
	The proposed proprietary name / brand name	**Ondanz 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ondansetron as Hcl Dihydrate…4mg
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Onset tablet by M/s Pharmedic (Pvt) Ltd.
	Proposed Pack size	As per SRO

-Evaluation by PEC:

Section#	Observations	Firm's response
1.1	Form 5F has been submitted from the contract manufacturer instead of the contract giver.	
1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	
3.2.S.4.3	Drug substance analytical method verification studies shall be submitted from the drug product manufacturer.	
3.2.P.2.2.1	• Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product. • Details of the manufacturer of the competitor product used for performance of Pharmaceutical equivalence and CDP studies shall be submitted. • CDP studies have been submitted for 8mg strength instead of 4mg tablet.	
3.2.P.3.5	• Submitted process validation protocol is for 8mg strength instead of 4mg tablet.	
3.2.P.5.2	• Submit drug product analytical procedure from M.s Weather folds instead of submitting USP monograph extract. • Test number of the dissolution test adopted for the drug product batch release, from the USP monograph, shall be specified.	
3.2.P.6	COA of reference/working standard, used for analysis of the drug product stability batches, shall be submitted.	

3.2.P.8.3	• Submitted analytical chromatogram does not declare the wavelength upon which the analysis has been performed. • Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance. • Details of batch size and manufacturing date are different between COAs submitted in section 3.2.P.5.4 and stability sheets in section 3.2.P.8.3 • Submit raw data sheets for stability studies declaring the concentration of sample and standard preparations in Assay & dissolution test.	

Decision of 339th meeting: Deferred for submission of reply to above cited shortcomings.

Reply by the firm:
The firm has referred the minutes of 343rd meeting of Registration. The applied product manufactured by M/s Weather Folds Pharmaceuticals was approved on Form 5F.
Following are the details of the approved product.
Application form: Form 5F
Diary Number: Dy.No 16609 dated 04-07-2023
Meeting: 343rd

Decision: Approved.

4.	Name, address of Applicant / Marketing Authorization Holder	M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 15687 dated 21-06-2023
	Details of fee submitted	Rs.75,000/- dated 07-06-2023
	The proposed proprietary name / brand name	**Ondanz 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ondansetron as Hcl Dihydrate…8mg
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Onset tablet by M/s Pharmedic (Pvt)
		Ltd.
	Proposed Pack size	As per SRO

Evaluation by PEC:

Section#	Observations	Firm's response
1.1	Form 5F has been submitted from the contract manufacturer instead of the contract giver.	

1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	
3.2.S.4.3	Drug substance analytical method verification studies shall be submitted from the drug product manufacturer.	
3.2.P.2.2.1	• Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product. • Details of the manufacturer of the competitor product used for performance of Pharmaceutical equivalence and CDP studies shall be submitted. • CDP studies have been submitted for 4mg strength instead of 8mg tablet.	
3.2.P.3.5	• Submitted process validation protocol is for 8mg strength instead of 4mg tablet.	
3.2.P.5.2	• Submit drug product analytical procedure from M.s Weather folds instead of submitting USP monograph extract. • Test number of the dissolution test adopted for the drug product batch release, from the USP monograph, shall be specified.	
3.2.P.6	COA of reference/working standard, used for analysis of the drug product stability batches, shall be submitted.	
3.2.P.8.3	• Submitted analytical chromatogram does not declare the wavelength upon which the analysis has been performed. • Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance.	
	• Submit raw data sheets for stability studies declaring the concentration of sample and standard preparations in Assay & dissolution test.	

Decision of 339th meeting: Deferred for submission of reply to above cited shortcomings.

Reply by the firm:
The firm has referred the minutes of 343rd meeting of Registration. The applied product manufactured by M/s Weather Folds Pharmaceuticals was approved on Form 5F.
Following are the details of the approved product.
Application form: Form 5F
Diary Number: Dy.No 16611 dated 04-07-2023
Meeting: 343rd

Decision: Approved.

5.	Name, address of Applicant / Marketing Authorization Holder	M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 15685 dated 21-06-2023
Details of fee submitted	Rs.75,000/- dated 07-06-2023
The proposed proprietary name / brand name	**Ondanz 4mg/5ml Syrup**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ondansetron as HCl Dihydrate…4mg
Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
Reference to Finished product specifications	Innovator's
The status in reference regulatory authorities	MHRA Approved
For generic drugs (me-too status)	
Proposed Pack size	As per SRO

Evaluation by PEC:

Section#	Observations	Firm's response
1.1	Form 5F has been submitted from the contract manufacturer instead of the contract giver.	
1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	
3.2.S.4.3	Drug substance analytical method verification studies shall be submitted from the drug product manufacturer.	
3.2.P.2.2.1	• Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product. • Details of the manufacturer of the competitor product used for performance of Pharmaceutical equivalence studies shall be submitted.	
3.2.P.3.4	Submitted details are for the Phytonadione while the applied • formulation is of Ondansetron Syrup.	
3.2.P.3.5	Submitted process validation protocol include details for the tablet dosage form instead of the applied syrup.	
3.2.P.5.2	Submit drug product analytical procedure from M.s Weather folds instead of submitting USP monograph extract.	
3.2.P.6	COA of reference/working standard, used for analysis of the drug product stability batches, shall be submitted.	
3.2.P.8.3	• Submitted analytical chromatogram does not declare the wavelength upon which the analysis has been performed. • Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance. • Submit raw data sheets for stability studies declaring the concentration of sample and standard preparations in Assay test. Microbiological reports shall be submitted for the Microbial Enumeration test performed during stability studies.	

Decision of 339th meeting: Deferred for submission of reply to above cited shortcomings.

Reply by the firm: The firm has referred the minutes of 343rd meeting of Registration. The applied product manufactured by M/s Weather Folds Pharmaceuticals was approved on Form 5F. Following are the details of the approved product. Application form: Form 5F Diary Number: Dy.No 15684: 21-06-2023 Meeting: 339th		
Decision: Approved.		
6.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form + Strength	Emgly 25mg Tablet
	Composition	Each film coated tablet: Empagliflozin…..25mg
	Diary No. Date of R& I & fee	From-5 Dy. No. 179 dated 03-02-2017 50,000/- dated 02-02-2017
	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5-D
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size & MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 25mg tablets of M/s The Searle Company
	GMP status	Submitted, Certificate No. 007/2022-DRAP (K), Dated: 20-01-2022. (Valid for 2 years).
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Emgly 25mg Tablet
Manufacturer of API	Chifeng Arker Pharmaceutical Technology Co. Ltd. Address: No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China.
API Lot No.	D86-200401
Description of Pack (Container closure system)	3x10's, Alu-Au Blister
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 75% ± 5%
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (months)

	Real Time: 0, 3, 6, (months)		
Batch No.	PLT-T-139	PLT-T-140	EXP-T-1074
Batch Size	2000 Tablets	2000 Tablets	1000 Tablets
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	03.2021	03.2021	03.2021
No. of Batches	03		
Date of Submission	Dy. No. 31022 dated 01-11-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA of the drug substance (Empagliflozin) from M/s. Chifeng Arker Pharmaceutical Technology Co. Ltd. Firm has also submitted COA of the drug substance with batch number D87-200401 and manufacturing date Jan-22. (Manufacturer's **Specification)**
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Analytical procedures for the drug substance from both drug substance manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has Submitted GMP Certificate Vald till 21-05-2023. Issued by Inner Mangolia Pharmaceutical Industry Association. (Not acceptable to DRAP)
6.	Documents for the procurement of API with approval from DRAP (in case of import).	API Procurement In-voice attached. Invoice No. PSPW-200429-2, Invoice cleared by DRAP Karachi office. Dated, 19-05-2020.
7.	Protocols followed for conduction of stability study.	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted 3 months stability data (Accelerated and Real time).

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

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
4.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
5.	Complete batch manufacturing record of three stability batches shall be submitted..	
6.	Record of comparative dissolution data shall be submitted.	
7.	Submit valid GMP certificate of Barret Hodgson Pakistan (Pvt) Ltd.	
8.	Submit real time and accelerated stability data on 6 month time point. (As your firm's dossier only contains till 3 month time point)	
9.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

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

The firm has submitted the reply vide application ID **9BX-REN-EGLQ** dated 26-06-2025.

Observation	Reply by the firm
Reference of previous approval of applications with stability study data of the firm shall be submitted.	Sacval (Sacuitril+Valsartan) tablet 344th meeting.
Stability study data of API from API manufacturer shall be submitted.	06 months accelerated and 24 months real time stability data of 03 batches according to one IV-A.
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	DML No 20160053 valid is 28-12-2025 is submitted.
Drug-excipients compatibility studies (where applicable) shall be submitted.	N.A Same excipient as used by innovator.
Complete batch manufacturing record of three stability batches shall be submitted..	Submitted,
Record of comparative dissolution data shall be submitted.	Submitted against Jardiance.

Submit valid GMP certificate of Barret Hodgson Pakistan (Pvt) Ltd.	GMP certificate issued on the basis of inspection conducted on 17-11-2025.
Submit real time and accelerated stability data on 6 month time point. (As your firm's dossier only contains till 3 month time point)	Submitted along with audit trail report.
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.
Decision: Approved. The firm shall submit applicable fee for correction of specifications to Innovaotr's.	

7.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharma plot no. 122, Block-a, Phase-v, Industrial Estate Hattar
	Brand Name +Dosage Form + Strength	Denset 2mg Tablet
	Composition	Each Tablet Contains: Dienogest 2mg
	Diary No. Date of R& I & fee	Dy. No.14565 dated 07-03-2019, Rs: 20,000/- dated 07-03-2019
	Pharmacological Group	Progestogens
	Type of Form	Form 5
	Finished product Specifications	Not submitted
	Pack size & Demanded Price	2 x 10's
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Not submitted; not available in database
	GMP status	GMP certificate issued based upon inspection conducted on 03-04-2023.
	Remarks of evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of requisite manufacturing facility / section approval from Licensing Division.
	Decision of 323rd meeting of RB:	Deferred for following submissions:

		• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board. • Evidence of requisite manufacturing facility / section approval from Licensing Division. • Reference of finished product specifications.

STABILITY STUDY DATA

Manufacturer of API	M/s SWATI SPENTOSE PVT .LTD A-1/2111, PHASE III , G.I.D.C.-VAPI ,GUJARAT -396 195 , INDIA		
API Lot No.	Deinogest: DNG/921005		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0,3, 6 (months)		
Batch No.	DG-01	DG-02	DG-03
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	28-05-2022	28-05-2022	28-05-2022
No. of Batches	03		
Date of Submission of stability data	Dy No.39575 Dated 30-12-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

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

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (DNG/921005) of API (Dienogest) from M/S SWATI SPENTOSE PVT .LTD A-1/2111, PHASE III , G.I.D.C.-VAPI ,GUJARAT -396 195 , INDIA and M/S Wnsfeild Pharma Plot No. 122, Block-A, Phase-V, Industrial Estate Hattar
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Methods used for analysis of APIs from both API Manufacturer and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	For Dienogest: Firm has submitted copy of GMP certificate dated 17-10-2022 in the name of M/S SWATI SPENTOSE PVT .LTD A-1/2111, PHASE III , G.I.D.C.-VAPI ,GUJARAT -396 195 , INDIA issued by FDA GUJARAT INDIA. Valid till 16-10-2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	For Dienogest: The firm has submitted copy of invoice No. FHPL/20210901 dated 14-03-2022 from exporter M/S SWATI SPENTOSE PVT .LTD A-1/2111, PHASE III , G.I.D.C.-VAPI ,GUJARAT -396 195 , INDIA, for import of 12gs of DIENOGEST (Batch No. 921005) in name of M/s Wnsfeild Pharmaceuticals Hattar. Form-6 issued by AD (I&E) DRAP Peshawar dated 27-04-2022 is also submitted
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[xxiii]:
Applicant shall submit the following:

Sr. No.	Observations/Shortcoming

i.	Tablet (steroidal hormone) section was granted vide letter dated 13-01-2019 but is not included in the list of sections renewed vide letter dated 11-06-2024. Applicant shall justify and submit evidence of requisite manufacturing facility / section approval from Licensing Division, DRAP.
ii.	Reference of finished product specifications shall be submitted.
iii.	Stability study data of API from API manufacturer
iv.	Drug-excipients compatibility studies (where applicable)
v.	Complete batch manufacturing record of three stability batches.
vi.	Record of comparative dissolution data (where applicable)

Decision of 344th meeting: Deferred for submission of response to above mentioned shortcomings.

The firm has submitted the reply vide online application ID No. 1EX-EYE-JVHT.

Reason	Reply
Tablet (steroidal hormone) section was granted vide letter dated 13-01-2019 but is not included in the list of sections renewed vide letter dated 11-06-2024. Applicant shall justify and submit evidence of requisite manufacturing facility / section approval from Licensing Division, DRAP.	"The inspection of all sections was conducted jointly at the time of issuance of the Section Approval Lette the DML, the approval letters for some manufacturing Tablet Steroidal Hormones were with policy decisions by the CLB. And the letter afterwards separately. Section Approval Letter is A your kind reference please." The firm has submitted Tablet Section (Steroidal-H approval letter NO. F.3-2/2006-Lic(Vol-II) dated 16
Reference of finished product specifications shall be submitted.	As per innovator's
Stability study data of API from API manufacturer	06 months accelerated and 24 months real time stab according to zone IV-A.
Drug-excipients compatibility studies (where applicable)	Excipients are same as the product approved in Hea
Complete batch manufacturing record of three stability batches.	Submitted
Record of comparative dissolution data (where applicable)	Submitted against Visanne 2mg tablet by M/s Baye
Decision: Approved.	

8.	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 19216 dated 03-08-2023
	Details of fee submitted	Rs.30,000/- dated 23-05-2023
	The proposed proprietary name / brand name	**Empozin-M XR 12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg (as Immediate Release) Metformin HCl…1000mg (as Extended Release)
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Xenglu Met XR tablet of M/s Hilton
	Proposed Pack size & Price	14's & 28's: As per SRO
	Reference to Finished product specifications	Innovator specifications
9.	**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 18303 dated 20-07-2023
	Details of fee submitted	Rs.30,000/- dated 23-05-2023
	The proposed proprietary name / brand name	**Empozin-M XR 10/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…10mg (as Immediate Release) Metformin HCl…1000mg (as Extended Release)
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03

	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Xenglu Met XR tablet of M/s Hilton
	Proposed Pack size & Price	14's & 28's: As per SRO
	Reference to Finished product specifications	Innovator specifications
10.	**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 18302 dated 20-07-2023
	Details of fee submitted	Rs.30,000/- dated 23-05-2023
	The proposed proprietary name / brand name	**Empozin-M XR 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…5mg (as Immediate Release) Metformin HCl…1000mg (as Extended Release)
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Xenglu Met XR tablet of M/s Hilton
	Proposed Pack size & Price	14's & 28's: As per SRO
	Reference to Finished product specifications	Innovator specifications
11.	**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 18304 dated 20-07-2023
	Details of fee submitted	Rs.30,000/- dated 23-05-2023
	The proposed proprietary name / brand name	**Empozin-M XR 25/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…25mg (as Immediate Release) Metformin HCl…1000mg (as Extended Release)
	Pharmacotherapeutic Group of (API)	**Metformin HCl:**

		Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Xenglu Met XR tablet of M/s Hilton
	Proposed Pack size & Price	14's & 28's: As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC:

Sr.#	Section#	Observation	Firm's response
1.	**1.5.6**	Relevant information shall be submitted for the reference of drug product specifications.	
2.	**1.6.5**	Valid DML/GMP certificate of the drug substance manufacturers issued by relevant regulatory authority of country of origin shall be submitted.	
3.	**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.	
4.	**3.2.S.4**	• Justification shall be submitted for the variation in limits of Solubility test between the drug substance specifications of Empagliflozin submitted from M/s Fuxin Long Rui and M/s Macter. • Justification shall be submitted for variation chromatographic conditions applied for Assay test between the analytical procedure submitted from M/s Fuxin Long Rui and M/s Macter. • COA of Empagliflozin from M/s Macter is of different batch number than that of M.s Fuxin Long Rui. • COA of Empagliflozin from M/s Fuxin long Rui declares solubility as "Insoluble in water", while COA of Empagliflozin form M/s Macter declares solubility "very slightly soluble in water". Justification shall be submitted for this variation.	
5.	**3.2.S.7**	• Long term stability studies data of Empagliflozin shall be submitted till claimed shelf life as per Zone IV a conditions. • Long term stability studies shall be submitted as per Zone IV conditions for Metformin HCl.	
6.	**3.2.P.2.1**	Justification shall be submitted for the declared quantity of 28.75mg per tablet for Empagliflozin in the proposed master formulation against the label claim of 25mg.	
7.	**3.2.P.2.2.2**	Justification shall be submitted on basis of performance based evidence for adding 15% overage of "Empagliflozin" in the applied batch formulation	
8.	**3.2.P.3.5**	• Submitted process validation protocol does not include details of in-process test for establishing dissolution profile of Metformin HCl at core stage. Justification shall be submitted in this regard. • Details shall be submitted for the in-process test applied to establish the fact that required content of Empagliflozin	

		has been layered onto the core tablet, before proceeding for the final film coat.	
9.	**3.2.P.5.2**	Justification shall be submitted for applying different concentrations of standard and sample solutions in Assay test.	
10.	**3.2.P.5.3**	• 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". • Specificity of UV spectrophotometric method of Dissolution test for Metformin HCl shall be established with respect to the absorbance of Empagliflozin in the sample solution.	
11.	**3.2.P.6**	COA of reference/working standards of drug substances, used for the analysis of drug product shall be submitted.	
12.	**3.2.P.8.3**	Documents confirming procurement of Empagliflozin shall be submitted with the approval of DRAP I&E office shall be submitted.	
13.	**2.3.R**	Justify the quantity of drug substances dispensed for manufacturing of stability batches considering the label claim and potency of drug substance determined in drug substance analysis.	

Decision of 340th meeting of Registration Board:
Deferred for submission of above cited shortcomings.

Response of the Firm:

Sr.#	Section#	Observation	Firm's response
1.	**1.5.6**	Relevant information shall be submitted for the reference of drug product specifications.	Firm informed that they comply Innovator's Specifications
2.	**1.6.5**	Valid DML/GMP certificate of the drug substance manufacturers issued by relevant regulatory authority of country of origin shall be submitted.	Firm submitted the valid GMP certificate of both APIs.
3.	**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.	Firm submit the revised specification, i.e. synchronized with DMF from Fuxin Long Rui Pharmaceutical along with testing reports.
4.	**3.2.S.4**	• Justification shall be submitted for variation chromatographic conditions applied for Assay test between the analytical procedure submitted from M/s Fuxin Long Rui and M/s Macter.	Firm in their response stated that there is error incorporated during method development phase. Please find the revised specification, i.e. synchronized with DMF from Fuxin Long Rui Pharmaceutical along with testing reports.

		• COA of Empagliflozin from M/s Macter is of different batch number than that of M.s Fuxin Long Rui. • COA of Empagliflozin from M/s Fuxin long Rui declares solubility as "Insoluble in water", while COA of Empagliflozin form M/s Macter declares solubility "very slightly soluble in water". Justification shall be submitted for this variation.	Firm in their response stated that there is error incorporated during method development phase. Please find the revised specification, i.e. synchronized with DMF from Fuxin Long Rui Pharmaceutical along with testing reports.
5.	**3.2. S.7**	• Long-term stability studies data of Empagliflozin shall be submitted till claimed shelf life as per Zone IV a condition. • Long-term stability studies shall be submitted as per Zone IV conditions for Metformin HCl.	Firm still not submitted the Long-term stability studies as per Zone IV conditions for Metformin HCl.
6.	**3.2.P.2.1**	Justification shall be submitted for the declared quantity of 28.75mg per tablet for Empagliflozin in the proposed master formulation against the label claim of 25mg.	Firm replied that the choice of 15% overage percentages reflects a well-considered approach to formulation, Based on previous performance & utilizing historical data from development of different functional coated products utilizing conventional coating system, guides decisions about API overage about and efficacy standards. 10-15 % to mitigate losses during the coating process, thus ensuring the final product meets quality 1. Coating process done in R&D conventional coating pan having capacity of coating 0.5 kg-10kg with single coating gun with 1.0 mm pore size 2. Gun distance from coating pan is kept 8-12 inches 3. Process loss occurs during spray volume setting 4. Process loss occur from exhaust system 5. Process losses occur as some of the coating material stick to the coating pan during coating process 6. Process losses occur as some of the coating material remains in the hoses and pipes of spray equipment and vessel after completion of coating process Due to above losses it is a general practice to include 15% excess at coating stage. As it is
7.	**3.2.P.2.2.2**	Justification shall be submitted on basis of performance based evidence for adding 15% overage of "Empagliflozin" in the applied batch formulation	

			functional coating, Weight gain is monitored during the process and coating process is stopped when the desired weight gain is achieved
8.	**3.2.P.3.5**	• Submitted process validation protocol does not include details of in-process test for establishing dissolution profile of Metformin HCl at core stage. Justification shall be submitted in this regard. • Details shall be submitted for the in-process test applied to establish the fact that required content of Empagliflozin has been layered onto the core tablet, before proceeding for the final film coat.	Dissolution at core stage is added along with Annexure 14 on pg. 18 of process validation protocol. Further, In process weight variation is added at coated stage for API coating (See Annexure 20, 21, 22).
9.	**3.2.P.5.2**	Justification shall be submitted for applying different concentrations of standard and sample solutions in Assay test.	The assay standard concentration differs only for Empagliflozin in 5/1000 mg and 25/1000 mg strengths, while it remains consistent for metformin. This is because a single standard is used for analyzing the assay across all strengths. The assay concentration was prepared based on the 12.5/1000 mg strength, where the Empagliflozin assay concentration is 0.125 mg/mL. The table below provides the assay concentrations of Empagliflozin samples for all strengths. Strength (mg) Standard conc. for Empaglif lozin (mg/mL) Sample conc. for Empaglif lozin (mg/mL) Remarks 5/1000 0.125 0.05 Different concentration 10/1000 0.125 0.10 Approximately same concentration 12.5/1000 0.125 0.125 Same concentration 25/1000 0.125 0.25 Different concentration During the method development stages, we conducted range studies from 25% to 250% of 0.125 mg/mL, which covered all the concentrations. Specifically, 25% of 0.125 mg/mL is 0.031 mg/mL, while 200% of 0.125 mg/mL is 0.25 mg/mL. Thus, the method's range adequately covers all required concentrations.
10.	**3.2.P.5.3**	• 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".	Firm replied that chromatograms are attached for peak purity with values which lies within the limits, shows our analyte Chromatographic peak is not attributable to more than one component. Further, During the development stages of method, it was made sure that at the wavelength of metformin no response form placebo or Empagliflozin was observed. Please find attachments of photometric reports proving that no response from the blank sample solution and placebo containing

		• Specificity of UV spectrophotometric method of Dissolution test for Metformin HCl shall be established with respect to the absorbance of Empagliflozin in the sample solution.	Empagliflozin is observed at 232nm. Highest absorbance received from placebo is 0.004 which is less than 2% absorbance of 100% sample's response of metformin.
11.	**3.2.P.6**	COA of reference/working standards of drug substances, used for the analysis of drug product shall be submitted.	Submitted
12.	**3.2.P.8.3**	Documents confirming procurement of Empagliflozin shall be submitted with the approval of DRAP I&E office shall be submitted.	Submitted
13.	**2.3.R**	Justify the quantity of drug substances dispensed for manufacturing of stability batches considering the label claim and potency of drug substance determined in drug substance analysis.	The calculation for the quantity of drug substances (Metformin HCl & Empagliflozin) dispensed for manufacturing of stability batches considering the label claim and potency of drug substance has been elaborated. See attachment.

Decision: The Board approved Empozin-M XR 25mg/1000mg, Empozin-M XR 5mg/1000mg, Empozin-M XR 12.5mg/1000mg and Empozin-M XR 10mg/1000mg.

Drug Regulatory Authority of Pakistan

(Pharmaceutical Evaluation & Registration Division)

******

Registration Board 361 Meeting Additional/Supplementary Minutes:

Sr. No	Title	Description
1	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Med Art, Pakistan** A-175 Block 13-C KDA scheme 24 Gulshan-e-Iqbal **(0403)**
	Application Form Dy. No / Tracking ID & date of submission	(H2D-MP3-V5EV, 2025-08-18)
	Detail of Fee Submitted	300000.0, 2025-07-17,
	The proposed proprietary name / brand name	**Sevofran**
	Label Claim	Each glass bottle contains.... Sevoflurane (100%) 250ml
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 glass type III bottle 250ml-Controlled
	Shelf Life (Unit)	2 Year(s)below 30 degree Centrigrade
	For generic drugs (me-too Status)	Sevorane (Sevoflurane) 250 ml (Getz Pharma (PVT)., Ltd) Reg. No. 027374
	Pharmacotherapeutic Group of (API)	N01AB08 Anesthesia
	Name, address of Manufacturing site:	Hana Pharm. Co., Ltd. -133, Jeyakgongdan 3-gil, Hyangnam-eup, Hwaseong-si, Gyeonggi-do-South Korea
	Pharmaceutical Equivalence and Comparative Dissolution Profile	----
	Name, address of Marketing Authorization Holder:	Hana Pharm. Co., Ltd. , 133, Jeyakgongdan 3-gil, Hyangnam-eup, Hwaseong-si, Gyeonggi-do, South Korea
	Details of Certificates (CoPP/FSC/cGMP):	GMP Certificate is issued from Ministry of Food and Safety, Republic of Korea
	Details of Authorization Letter :	COPP and agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	US FDA [Ultane (Sevoflurane) 250 ml Liquid Inhalation -Abbott Laboratories, Approval no. 020478s007, Approval Date: 12/11/2002]
	Evaluation Remarks	
	in initial submission pharmaceutical equivalence was not submitted. The firm was asked to submit pharmaceutical equivalence studies for further processing of their application. The firm submitted testing of their own product and submitted its comparison with quality parameters of innovator product. No reference product was tested alongside their own product to establish pharmaceutical equivalence. (theoretical pharmaceutical equivalence is submitted only based on available data of innovator product).	
	The firm was again asked to submit pharmaceutical equivalence studies as per ICH guidelines and in response the applicant has submitted following explanation of manufacturer;	

	"We Hana Pharm Co Ltd located at 133 Jeyakgomgdan 3-gil Hyangnam euo Hwaseong-si Gyeonggi Republic of Korea, declare as below regarding P9 product interchangeability. Since Sevofran 100% v/v Volatile liquid for inhalation is a gas for inhalation, a bioequivalence studies are not required according to the guideline on investigation of Bioequivalence (EMA, London, 20 January 2010, CPMP/EWP/QWP/1401/98 Rev.1)"	
	Decision	
	Approved As per policy for inspection abroad.	
2	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	**Ferozsons Laboratories Limited** PO Ferozsons, Amangarh **(000038)**
	Application Form Dy. No / Tracking ID & date of submission	(AD2-JJY-GVTR, 2026-05-12)
	Detail of Fee Submitted	313500, 2026-03-12,
	The proposed proprietary name / brand name	**Superia Capsule 65mg**
	Label Claim	Each capsule contains: Itraconazole granules equivalent to Itraconazole.....65mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10's (1x10's)-As per SRO,14's (2x7's)-As per SRO,20's (2x10's)-As per SRO,28's (4x7's)-As per SRO,30's (3x10's)-As per SRO,4's (1x4's)-As per SRO,5's (1x5's)-As per SRO,7's (1x7's)-As per SRO,8's (2x4's)-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Manufacturer Name: Lee Pharma Limited Manufacturer Address: Plot No. V, Phase II, VSEZ, Duvvada, Sabbavaram (M), Visakhapatnam District – 530049, Andhra Pradesh
	Detail of stability batches of drug product	03 batches manufactured each having batch size i.e 833 Capsules
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-06 (issued dated 13-11-2024, specifies 1.625 kg import of (Itraconazole Granules 40%), Form-06, Clearance certificate, Goods Declaration, Form-03 are attached in Module 03, Section 3.2.P, Sub-section 3.2.P.8.3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies are conducted against Tolsura 65mg Capsules (Batch No: FG14773, Exp. Date: 04/2026) of Mayne Pharma detail report is attached in Section 3.2.P, Sub-section 3.2.P.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data studies of 03 batches is performed by Drug substance manufacturer attached at Module 03 Section 3.2.S.7
	The status in reference regulatory authorities	Brand Name: Tolsura Capsules 65mg Approval granted to: Mayne Pharma-USFDA
	GMP status of the firm	Complying cGMP as per Certificate No. F.11-10/2024-DRAP-435 Dated: 26-11-2024, valid till 09-08-2027

	Evidence of approval of manufacturing facility	Renewal of DML granted online via e-App tracking ID: XWU-WU3-4VZM dated: 01-08-2025 by DRAP, inlcuding Capsule Section (General)
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
3	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	**Macter International Limited** F-216,S.I.T.E.,Karachi-Pakistan **(000141)**
	Application Form Dy. No / Tracking ID & date of submission	(4ER-BXQ-2Z4B, 2025-01-30)
	Detail of Fee Submitted	75000.0, 2024-12-05,
	The proposed proprietary name / brand name	**Milast 0.3% Cream**
	Label Claim	Each gram contains; Roflumilast.....3mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10,15,20,25 and 60gm-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 20°C to 25°C (excursions permitted between 15°C and 30°C).
	For generic drugs (me-too Status)	NOT APPLICABLE SINCE THIS IS A NEW DRUG"
	Pharmacotherapeutic Group of (API)	Other antipsoriatics for topical use D05AX06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Chongqing Huapont Shengchem Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches, 90 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Zoryve Cream 0.3% B. No. THBS-A Mfg Acrutis Biotherapeutic
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Zoryve Cream by Arcutis (FDA approved) Biotherapeutics, Inc.
	GMP status of the firm	Renewal inspection in 2025
	Evidence of approval of manufacturing facility	Section approval letter (Renewal) dated 06.10.2025 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
4	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(5GB-EG3-SJ4V, 2024-08-15)

	Detail of Fee Submitted	75000.0, 2024-06-26,
	The proposed proprietary name / brand name	**Dyotra-D 10mg Tablet**
	Label Claim	COMPOSITION: Each Film Coated Tablet contains: DYDROGESTERONE.....10MG (Product Complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	Duphaston 10mg Tablet by Abbot Laboratories
	Pharmacotherapeutic Group of (API)	PROGESTOGENS G03DB01
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	2 batches, 10000 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	Duphaston10mgTablet B. No 201392
	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	Submitted
	Evidence of approval of manufacturing facility	Tablet Section steroidal hormone approved vide letter dated 27.06.2019
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
5	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala **(000987)**
	Application Form Dy. No / Tracking ID & date of submission	(57Y-4MY-H9QG, 2025-03-12)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-26, 2024-12-07
	The proposed proprietary name / brand name	**Dyotra-D 10mg Tablet**
	Label Claim	Each Film Coated Tablet contains: DYDROGESTERONE.....10MG (Product Complies Innovator's 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)	Duphaston by Abbott Laboratories
	Pharmacotherapeutic Group of (API)	PROGESTOGENS G03DB01
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	2 batches, 10000 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	Duphaston10mgTablet B. No 201392
	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	Submitted
	Evidence of approval of manufacturing facility	Tablet Section steroidal hormone approved vide letter dated 27.06.2019
	Evaluation Remarks	
	Duplicate application with tracking ID QUL-6XB-UQRD	
	Decision	
	Rejected	
6	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala **(000987)**
	Application Form Dy. No / Tracking ID & date of submission	(QUL-6XB-UQRD, 2024-08-09)
	Detail of Fee Submitted	75000.0, 2024-06-26,
	The proposed proprietary name / brand name	**Dyotra-D 10mg tablet**
	Label Claim	Each Film Coated Tablet contains: Dydrogesterone (USP).....10mg (Product Complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Duphaston by Abbott Laboratories
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	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	
	Application fulfills codal formalities and can be considered by board. The application is duplicate with another application vide tracking ID 57Y-4MY-H9QG. In this application firm has submitted response to all the queries which were communicated, but fee submitted is less than that for application of contract manufacturing. In Application vide tracking ID 57Y-4MY-H9QG firm has submitted differential fee. Product and details, everything is same in both applications.	

	Decision	
	Approved	
7	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Biogen Life Sciences** 8-KM, Chak Beli Road, Rawat, **(000911)**
	Application Form Dy. No / Tracking ID & date of submission	(NMQ-U9T-WA17, 2025-03-11)
	Detail of Fee Submitted	37000.0, 2025-01-27,
	The proposed proprietary name / brand name	**Valolog Plus Cream**
	Label Claim	Each gram contains: Nystatin USP..... 100,000 units Neomycin Sulphate equivalent to Neomycin..... 2.5mg Gramicidin..... 0.25mg Triamcinolone Acetonide..... 1mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20gm-As per SRO
	Shelf Life (Unit)	3 Year(s)Room Temperature
	For generic drugs (me-too Status)	Manufacturer Name GSK Brand Name Kenacomb Cream Strength 20g Composition Each gram contains: Nystatin USP…….. 100,000 units Neomycin Sulphate USP equivalent to…….. 2.5mg base Gramicidin
	Pharmacotherapeutic Group of (API)	--
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Company Name: ANTIBIOTICE S.A. Address: 1 Valea Lupului Street, Iasi 707410, ROMANIA,Manufacture: FARMABIOS S.p.A. Address: Via Pavia, 1 27027 Gropello Cairoli, (PV) Italy,Sichuan Long March Pharmaceutical Co., Ltd. 448 Changqing Road, Leshan, Sichuan 614000, P.R. China,Xellia Pharmaceuticals USA, LLC Attn.: Eugenia Poulos 2150 E Lake Cook Rd, Suite 1015 Page 44 of 50 Buffalo Grove IL USA 60089
	Detail of stability batches of drug product	3 batches, 150 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	APIs taken loan from M/s Davis and Valor pharma. Clearance certificates are submitted along with loan documents.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Kenacomb 20g Cream, B. No. K88C Mfg GSK Pakistan Mfg Date 11.2022
	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	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	

8	Case Category	Routine (Adil Saeed)
	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	(ATW-S75-4GL5, 2025-05-06)
	Detail of Fee Submitted	75000.0, 2025-01-07,
	The proposed proprietary name / brand name	**Mevaten Capsule 5mg**
	Label Claim	Each hard capsule contains: Mavacamten.....5mg
	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 BELOW 30 C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	C01EB24 Other cardiac preparations
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anhui Haikang Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches, 1000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Camzyos 5mg B. No. CMMYKA2 Mfg BMS Ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	FDA
	GMP status of the firm	GMP certificate issued on basis of inspection dated 14.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 16.11.2022 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
9	Case Category	Routine (Adil Saeed)
	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	(ASU-2EQ-HJDV, 2025-05-06)
	Detail of Fee Submitted	75000.0, 2025-01-07,
	The proposed proprietary name / brand name	**Mevaten Capsule 2.5mg**
	Label Claim	Each hard capsule contains: Mavacamten.....2.5mg
	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 BELOW 30 C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	C01EB24 Other cardiac preparations
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	Anhui Haikang Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches, 1000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Camzyos 2.5mg B. No. CMDBPG2 Mfg BMS Ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted.
	The status in reference regulatory authorities	FDA
	GMP status of the firm	GMP certificate issued on basis of inspection dated 14.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 16.11.2022 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
10	Case Category	Routine (Adil Saeed)
	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	(NPR-R9R-P95G, 2025-05-06)
	Detail of Fee Submitted	75000.0, 2025-01-07,
	The proposed proprietary name / brand name	**Mevaten Capsule 15mg**
	Label Claim	Each hard capsule contains: Mavacamten.....15mg
	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 BELOW 30 C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	C01EB24 Other cardiac preparations
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anhui Haikang Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches, 1000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Camzyos 15mg B. No. CMNYKB2 Mfg BMS Ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted.
	The status in reference regulatory authorities	FDA
	GMP status of the firm	GMP certificate issued on basis of inspection dated 14.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 16.11.2022 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	

	Approved	
11	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Biogen Life Sciences** 8-KM, Chak Beli Road, Rawat, **(000911)**
	Application Form Dy. No / Tracking ID & date of submission	(TB9-YJP-Y86X, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2023-08-01,
	The proposed proprietary name / brand name	**Amikagen 100mg/2ml Injection**
	Label Claim	Each 2ml Vial Contains: Amikacin Sulfate eq. to Amikacin.....100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Condition
	For generic drugs (me-too Status)	Grasil 100mg Injection SAMI Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Other aminoglycosides J01GB06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Jinhua Conba Bio-pharm. Co., Ltd.
	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)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Gracil 100mg/2ml Injection
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	AMIKACIN 100mg/2ml Injection MHRA Approved
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
12	Case Category	Routine (Adil Saeed)
	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	(YAD-HNT-WSWD, 2025-02-04)
	Detail of Fee Submitted	75000.0, 2025-01-07,
	The proposed proprietary name / brand name	**Mevaten Capsule 10mg**
	Label Claim	Each hard capsule contains: Mavacamten.....10mg
	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 BELOW 30 C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	C01EB24 Other cardiac preparations

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anhui Haikang Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches, 1000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Camzyos 10mg B. No. CNHYZB2 Mfg BMS Ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	FDA
	GMP status of the firm	GMP certificate issued on basis of inspection dated 14.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 16.11.2022 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
13	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(LAW-JTR-AV42, 2024-10-08)
	Detail of Fee Submitted	75000.0, 2024-09-20,
	The proposed proprietary name / brand name	**Estadol Actifast 500mg tablet**
	Label Claim	Each tablet contains: Paracetamol .....500mg (As per Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic 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 Health Products Regulatory Authority (HPRA) of Ireland Panadol ActiFast Tablets 500mg.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

Deferred

The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points;

1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms.
2. Same R&D Manager (Ms. Naheed Yousaf) has signed documents of both firms.
3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms.
4. Same data logger sheets are submitted in cases of both firms.

14	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(6B2-MNA-XT7E, 2025-04-21)
	Detail of Fee Submitted	30000.0, 2024-08-06,
	The proposed proprietary name / brand name	**Danazol Capsule 200mg**
	Label Claim	Each Capsule contains: Danazol USP.....200 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10’s , 15’s, 20’s, 3-As per SRO
	Shelf Life (Unit)	2 Yearstore at 25C
	For generic drugs (me-too Status)	Danzol by Platinum Pharmaceuticals
	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	Danocrine by sanofi-aventis U.S. LLC
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	1. Valid, GMP certificate clearly referencing Danazol (Steroidal Drug Substance), and having similar address as mentioned in section 3.2.S.2.1 of dossier. 2. Link to verify excipients of reference product are similar to applied product.	
	Decision	
	Deferred Registration Board decided to defer the case for the following: 1. Valid, GMP certificate clearly referencing Danazol (Steroidal Drug Substance), and having similar address as mentioned in section 3.2.S.2.1 of dossier OR letter for change in address of drug substance manufacturer from concerned regulatory authority of country of origin.	

	2. Link to verify excipients of reference product are similar to applied product.	
15	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	**Ipram International** Plot # 26, S S 3, National Industrial Zone Rawat. **(000551)**
	Application Form Dy. No / Tracking ID & date of submission	(UHT-RGU-M98L, 2026-06-15)
	Detail of Fee Submitted	38700, 2026-06-09,
	The proposed proprietary name / brand name	**Ibuleue Tablet**
	Label Claim	Each Sugar-Coated Tablet Contains: Ibuprofen.....200mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Bludol 200mg Tablet
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zenith Chemical Industries Pvt Ltd.
	Detail of stability batches of drug product	See Enclosed
	Documents for the procurement of API with approval from DRAP (in case of Import)	See Enclosed
	Pharmaceutical Equivalence and Comparative Dissolution Profile	See Enclosed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	See Enclosed
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	See Enclosed
	Evidence of approval of manufacturing facility	See Enclosed
	Evaluation Remarks	
	Decision	
	Approved	
16	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	**Ipram International** Plot # 26, S S 3, National Industrial Zone Rawat. **(000551)**
	Application Form Dy. No / Tracking ID & date of submission	(XXE-EMB-GDB2, 2026-06-15)
	Detail of Fee Submitted	38700, 2026-06-09,
	The proposed proprietary name / brand name	**Ibuleue Tablet 400mg**
	Label Claim	Each film-coated tablet contains: Ibuprofen.....400mg (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)Room Temperature
	For generic drugs (me-too Status)	Semorfen Tablet 400mg
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zenith Chemical Industries Pvt Ltd.
	Detail of stability batches of drug product	See Enclosed

	Documents for the procurement of API with approval from DRAP (in case of Import)	See Enclosed
	Pharmaceutical Equivalence and Comparative Dissolution Profile	See Enclosed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	See Enclosed
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	See Enclosed
	Evidence of approval of manufacturing facility	See Enclosed
	Evaluation Remarks	
	Decision	
	Approved	
17	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	(ZX2-687-XA6J, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Baclo 10mg Tablet**
	Label Claim	Each 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 YearDo not store above 25°C
	For generic drugs (me-too Status)	Baclin 10mg Tablet by Genome Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	gamma-aminobutyric acid (GABA) 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	Lioresal 10mg Tablet by Novartis Ireland Limited
	Detail of previous approval	Baclosol 10mg Tablets, DRB 357
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
18	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	(ZVA-MPU-M529, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-20,
	The proposed proprietary name / brand name	**Cefalee**
	Label Claim	Each vial contains: Ceftaroline Fosamil (with L-Arginine) .....600mg (As per Innovators specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C. Store in the original package in order to protect from light.
	For generic drugs (me-too Status)	seraph pharmaceuticals
	Pharmacotherapeutic Group of (API)	Qingdao Xinnuo Pharmaceutical Chemical Co., Ltd. 50 meters North Yuanhou Neighborhood Committee Xifuzhen Street Chenyang Area Qingdao Shandong, CHINA
	Name, address of Manufacturing site:	Seraph pharmaceuticals-plot no 210, Industrial triangle kahuta road Islamabad pakistan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	330 meeting, Ceffosa 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 Approved	
19	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	(ZHP-27L-BBPZ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-12,
	The proposed proprietary name / brand name	**LOTEMAX 0.5% Ophthalmic Suspension**
	Label Claim	Each ml contains: Loteprednol Etabonate ....5.0mg (Innovator's Specs.).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at 30C.
	For generic drugs (me-too Status)	Tobol Ophthalmic Suspension by MEDICAIDS PAKISTAN PVT LTD

	Pharmacotherapeutic Group of (API)	Ophthalmic Anti-inflammatory Agent (Corticosteroid)
	Name, address of Manufacturing site:	OPTIMUS LABORATORIES (Pvt). Ltd.-Plot no 62,Bhalwal Industrial Estate, Bhalwal, District Sargodha.-
	The status in reference regulatory authorities	MHRA Approved.
	Detail of previous approval	354th 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 Approved	
20	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(Z7G-TAU-A3NQ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-05,
	The proposed proprietary name / brand name	**Mirotar Tablet 10mg**
	Label Claim	Each Film Coated Tablet Contains: Mirogabalin Besylate eq.to Mirogabalin 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	3 Yearas required
	For generic drugs (me-too Status)	Mirogab 10mg Tablet by Wimits
	Pharmacotherapeutic Group of (API)	Gabapentinoid medication primarily used for the treatment of neuropathic pain
	Name, address of Manufacturing site:	WIMITS PHARMACEUTICALS (PVT). LTD - Sunder Industrial Estate Lahore, Pakistan-
	The status in reference regulatory authorities	Tarlige Tablets by Daiichi Sankyo PMDA Approved
	Detail of previous approval	Mirogab 10mg Tablet Approved in DRB 344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

	Approved	
21	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	(Z2Y-HWT-9XQ2, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Caverda 20mg Tablets**
	Label Claim	Each filmcoated tablet contains: Vardenafil Hydrochloride eq. to Vardenafil 20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30°C
	For generic drugs (me-too Status)	varda 20mg tablets 132426
	Pharmacotherapeutic Group of (API)	Urologicals Drugs used in erectile dysfunction ATC code: G04BE09. Vardenafil is an oral therapy for the improvement of erectile function in men with erectile dysfunction
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-Plot No 313 Industrial Triangle Kahuta road Islamabad-
	The status in reference regulatory authorities	Bayer Healthcare Bayer Pharmaceutical Corporation 400 Morgan Lane West Haven CT 06516 Made in Germany LEVITRA Vardenafil HCl tablets for oral use Tablets: 2.5 mg 5 mg 10 mg 20 mg Initial U S Approval: 2003
	Detail of previous approval	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 Approved	
22	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(YWB-QSU-HQ5B, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-21,
	The proposed proprietary name / brand name	**Varipride**
	Label Claim	Each tablet contains Levosulpiride 50mg
	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 Approved	
23	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**
	Application Form Dy. No / Tracking ID & date of submission	(YGD-WLL-V681, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-04,
	The proposed proprietary name / brand name	**NUNAC EYE DROPS 1mg/mL**
	Label Claim	Each ml of suspension contains: Nepafenac.....1mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 YearStore between 15°C to 25°C.
	For generic drugs (me-too Status)	Nepanac Ophthalmic Suspension
	Pharmacotherapeutic Group of (API)	Nonsteroidal anti-inflammatory (NSAID)
	Name, address of Manufacturing site:	M/S Winthrox Pharmaceuticals (Pvt) Ltd-K-291-A, S.I.T.E, Super Highway, Karachi-
	The status in reference regulatory authorities	NEVANAC
	Detail of previous approval	Minutes of 333th Drug Registration Board Meeting held on 19th-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 Approved	
24	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(Y82-PLM-7ZUP, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**Civacta 2.5gm injection**
	Label Claim	Each Vial Contains: Ceftazidime as Pentahydrate.....2000mg Avibactam as Sodium Salt.....500mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25c
	For generic drugs (me-too Status)	Zavicefta 2.5gm injection by Pfizer
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	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	Cefbact, DRB 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 Approved	
25	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CSH PHARMACEUTICAL - NORTH (PVT.) LTD** 38 INDUSTRIAL ESTATE HAYATABAD PESHAWAR **(000511)**
	Application Form Dy. No / Tracking ID & date of submission	(Y4N-YG5-7QP5, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-17,
	The proposed proprietary name / brand name	**Penum 500mg Injection**

	Label Claim	Each vial contains: Meropenem Trihydrate Eq. to Meropenem.....500mg (Blended with Sodium Carbonate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Dew-Max Pharmaceuticals (Pvt) Ltd -PLOT NO 6, STREET NO SS-4, MAIN INDUSTRIAL AREA, RAWAT, Islamabad -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-312
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
26	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	(XPM-GYV-2GJS, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-20,
	The proposed proprietary name / brand name	**Terbique Cream**
	Label Claim	Each gram contains: Terbinafine HCl..... 10mg (1%)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10gm-As per SRO,15gm-As per SRO,20gm-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:	Focus & Rulz Pharmaceuticals (Pvt) Ltd -Plot No.44 Industrial Triangle Kahuta Road Islamabad-
	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 Approved	
27	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Medley Pharmaceuticals** 41-A PSIE Jhang Bahter Road ,Wah Cantt,Rawalpindi . **(000237)**
	Application Form Dy. No / Tracking ID & date of submission	(XDT-HG1-697H, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Efatel 10mg Tablet**
	Label Claim	Each film coated tablet contains 10 mg of Dydrogesterone.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Dydrogest 10mg Tablet of M/s OBS Pakistan Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Genito Urinary system and sex hormones.
	Name, address of Manufacturing site:	Skywin Pharmaceutical Pvt. Ltd.-Plot # 01, AL Badar Idustrial Estate Phase II, Sheikhupura Road, Sheikhupura Sheikhupura-
	The status in reference regulatory authorities	Duphaston 10 mg film-coated tablets of M/s Mylan IRE Healthcare Limited, Duphaston 10 mg film-coated tablets ® is Approved in HPRA of Ireland.
	Detail of previous approval	D-Gest 10mg Tablet - 336th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
28	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Epoch pharma** Plot No 83-85 Sector 15 korangi Industrial Area **(000425)**
	Application Form Dy. No / Tracking ID & date of submission	(X9P-2JY-RY16, 2026-08-20)

	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**Panket Injection 30mg**
	Label Claim	Each ml of ampoule contains: Ketorolac Tromethamine.....30mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Toradol Injection Martin Dow Pvt. Ltd. Reg. no. 108584
	Pharmacotherapeutic Group of (API)	NSAIDs
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE Super Highway, Phase-II, Karachi-
	The status in reference regulatory authorities	Ketorolac Injection Manufactured by Pfizer (FDA Approved)
	Detail of previous approval	Qetotrom Injection approved in 357th 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 Approved	
29	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(X79-HJ4-ZEQ1, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**ONDANZ 8mg/4ml Injection**
	Label Claim	Each Ampoule (4mL) Contains: Ondansetron as Hydrochloride Dihydrate.....8mg (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 Yearbelow 25c
	For generic drugs (me-too Status)	Doston Injection by Vision Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Serotonin 5-Ht3 Receptor Antagonists
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Block B, Industrial Estate, Hattar-
	The status in reference regulatory authorities	UK MHRA
	Detail of previous approval	ONDANZ 8mg/4ml Injection, DRB 339
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
30	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	(X3L-G3N-G2PW, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-10,
	The proposed proprietary name / brand name	**TRIORAL SACHET**
	Label Claim	Each Sachet contains: Sodium Chloride.....2.6g Sodium Citrate Dihydrate.....2.9g Potassium Chloride.....1.5g Glucose anhydrous.....13.5g 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)	generic product
	Pharmacotherapeutic Group of (API)	Oral Rehydration Salt
	Name, address of Manufacturing site:	Carer Pharmaceuticals Industries -Plot #27,Main Road, Industrial Estate, Rawat-
	The status in reference regulatory authorities	WHO Approved
	Detail of previous approval	317 minutes of meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
31	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**

	Application Form Dy. No / Tracking ID & date of submission	(WMH-LQD-56AV, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-25,
	The proposed proprietary name / brand name	**Biltex 20mg Tablet**
	Label Claim	Each Film Coated 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 25c
	For generic drugs (me-too Status)	Bilaxten 20mg Tablet by Searle Pharma
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat. -
	The status in reference regulatory authorities	UK MHRA
	Detail of previous approval	BILTEX 20mg Tablet, DRB 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 Approved	
32	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(WH3-B13-VDPS, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-18,
	The proposed proprietary name / brand name	**BMIV 2.5mg Tablet**
	Label Claim	Each uncoated Tablet Contains: Nebivolol as Hydrochloride.....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 Yearbelow 30ºC.
	For generic drugs (me-too Status)	Ubutril Tablet 50mg by Weather folds pharmaceuticals 105351
	Pharmacotherapeutic Group of (API)	Angiotensin receptor blocker
	Name, address of Manufacturing site:	WELMARK PHARMACEUTICALS-PLOT NO. 122, PHASE-V, BLOCK-B, INDUSTRIAL ESTATE, HATTAR, KPK.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Nitren 2.5mg 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 Approved	
33	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(WAE-867-P1VY, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**Forbud 200/6mcg DPI Capsule**
	Label Claim	Each capsule contains: Budesonide.....200mcg Formoterol Fumarate Dihydrate.....6mcg Each delivered dose contains: Budesonide.....160mcg Formoterol Fumarate Dihydrate.....4.5mcg (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 YearStore Below 25c
	For generic drugs (me-too Status)	Venticort Rotacaps 200mg + 6mcg Highnoon Labs
	Pharmacotherapeutic Group of (API)	Long-Acting Beta Agonists
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot no. 69/1, Block-B, Phase I-II, Industrial Estate, Hattar-
	The status in reference regulatory authorities	UK MHRA Approved
	Detail of previous approval	Combrain, DRB 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	

34	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hi-Med Pharmaceuticals** 208C Sundar industrial estate Raiwind Road Lahore **(000884)**
	Application Form Dy. No / Tracking ID & date of submission	(W4P-Q39-1UX1, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-16,
	The proposed proprietary name / brand name	**Dufem 5mg Tablet**
	Label Claim	Each Tablet contains: Norethisterone.....5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	2 YearStore at below 30 degree celcius
	For generic drugs (me-too Status)	OBS Pharma (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Norethisterone, also known as norethindrone, is a synthetic progestational hormone belonging to the 19-nortestosterone-derived class of progestins
	Name, address of Manufacturing site:	Skywin Pharmaceuticals.-Plot no. 01 Albadar Industrial Estate Phase II Shaikhupora Road Lahore.-
	The status in reference regulatory authorities	Primolut N Tablet 5mg (Bayer plc 400 South Oak Way, Reading, Berkshire, RG2 6AD)
	Detail of previous approval	
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
35	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(V1V-Q8R-6E8N, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-17,
	The proposed proprietary name / brand name	**C-Dosin 4mg Capsules**
	Label Claim	Each Capsule contains: Silodosin .....4mg (Innovators Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C.
	For generic drugs (me-too Status)	Registered in Pakistan (Silorap 4mg capsules by Gets Pharma)

	Pharmacotherapeutic Group of (API)	M/S:Anhui Haikang Pharmaceutical co,ltd. Address:No.21 Huanchang west road Anqing city,Anhui province 246000(china)
	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	USFDA Approved
	Detail of previous approval	Siloton 4mg Capsules, 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 Approved	
36	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(V4X-YSY-TERR, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-21,
	The proposed proprietary name / brand name	**Esovar**
	Label Claim	Each Capsule contains: Enteric Coated Esomeprazole magnesium trihydrate pellets eq. to Esomeprazole....40mg
	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)	Nexium 40mg 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 Approved	
37	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(V72-ZYV-XUDD, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**Dexwil 60mg Capsule**
	Label Claim	Each Capsule Contains: Dexlansoprazole as Dual Delayed Release Pellets.....60mg (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 25c
	For generic drugs (me-too Status)	Dexxo Capsule by Weather Folds Pharma
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Dexzen, DRB 330
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
38	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(V7A-35A-7X66, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-25,
	The proposed proprietary name / brand name	**Lexzol 1% Cream**
	Label Claim	Each gm Cream Contains: Luliconazole..... 10 mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 25c
	For generic drugs (me-too Status)	Lunaz Cream 1% 120214 by Winbrains
	Pharmacotherapeutic Group of (API)	Imidazole & Triazole Derivatives
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Block B, Phase-I&II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Lunaz 1% Cream, DRB 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
39	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	(VR6-7RW-Q64D, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Aksofenac SR 100mg Tablets**
	Label Claim	Each Film Coated Tablet Contains; Diclofenac sodium.....100mg In sustained release formulation (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30s, As per SRO-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25°C.
	For generic drugs (me-too Status)	Voltral SR 100mg Tablets by Novartis Pharmaceutical corporation Karachi
	Pharmacotherapeutic Group of (API)	Anti-inflammatory Non- Steroids
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Diclofenac sodium by Dexcel Ltd USFDA Approved
	Detail of previous approval	REACT SR 100MG TABLETS, DRB 357
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
40	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	(UVT-36Y-ZSMY, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-03,
	The proposed proprietary name / brand name	**ISOCONAZOLE CAPSULE 100mg**
	Label Claim	Each Capsule contains: Itraconazole Immediate release Pellets 22 % w/w equivalent to Itraconazole 100mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4`s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30%
	For generic drugs (me-too Status)	Rolac 100mg Capsule Reg No 024491 MS Sami Pharma Karachi
	Pharmacotherapeutic Group of (API)	Anti - Fungal
	Name, address of Manufacturing site:	MS JINNAH PHARMACEUTICALS. PVT LTD-13-KM Lahore Road Multan-
	The status in reference regulatory authorities	SPORANOX 100 mg Capsule By Janssen Ortho LLC, Gurabo, Puerto Rico 00778 USFDA Approved
	Detail of previous approval	Reg No 12546 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 Approved	
41	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**
	Application Form Dy. No / Tracking ID & date of submission	(UTE-P4V-27T4, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-04,
	The proposed proprietary name / brand name	**PATAONE EYE DROPS**

	Label Claim	Each ml contains: Olopatadine as HCl .....2mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 YearStore between 15°C to 25°C. Protect from sunlight & moisture
	For generic drugs (me-too Status)	Ocudine Eye Drops
	Pharmacotherapeutic Group of (API)	antihistamine and mast cell stabilizer p
	Name, address of Manufacturing site:	M/S Winthrox Pharmaceuticals (Pvt) Ltd-K-291-A, S.I.T.E, Super Highway, Karachi-
	The status in reference regulatory authorities	PATADAY™ (olopatadine hydrochloride ophthalmic solution)
	Detail of previous approval	Olopton Eye drops, Minutes 339th Drug Registration Board held on 06 -08 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 Approved	
42	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**MRCK Pharmaceutical Laboratories (Pvt) Ltd** Plot No. 537-D&E, Sundar Estate, Raiwind Road Lahore **(000753)**
	Application Form Dy. No / Tracking ID & date of submission	(UGX-VWB-62XH, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-10,
	The proposed proprietary name / brand name	**Omipact 2.25gm Injection**
	Label Claim	Each vial contains: Piperacillin 2 grams (As Piperacillin Sodium) and Tazobactam 0.25 grams (As Tazobactam sodium)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Bosch Pharmaceutical Tanzo 039593
	Pharmacotherapeutic Group of (API)	Penicillin and Beta-Lactam antibiotic
	Name, address of Manufacturing site:	Fleming Pharmaceuticals-23- Km Lahore-Sheikhpura Road, Lahore.-
	The status in reference regulatory authorities	USFDA Approved https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=050684
	Detail of previous approval	Fletazo Inj. 2.25 g - Minutes 323 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 Approved	
43	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(UG6-NS2-A57W, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**Dexwil 30mg Capsule**
	Label Claim	Each Capsule Contains: Dexlansoprazole as Dual Delayed Release Pellets.....30mg (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 25c
	For generic drugs (me-too Status)	Dexxo Capsule by Weather Folds Pharma
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Dexzen, DRB 330
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
44	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**PERFECT PHARMA (PVT) LTD** 5Km, Manga Road, Raiwind, Lahore **(000469)**
	Application Form Dy. No / Tracking ID & date of submission	(UEZ-RP6-GRDG, 2026-08-20)

	Detail of Fee Submitted	97200, 2026-06-11,
	The proposed proprietary name / brand name	**MEROPARIN 1G Injection**
	Label Claim	Each vial contains: Meropenem trihydrate USP eq. to Meropenem.....1g (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year25
	For generic drugs (me-too Status)	MOPEN Injection
	Pharmacotherapeutic Group of (API)	Carbapenem
	Name, address of Manufacturing site:	DEW-MAX PHARMACEUTICAL PVT LTD-Plot # 6, St SS4, Main industrial area, Rawat, Islamabad, Pakistan-
	The status in reference regulatory authorities	(MERREM 1g Injection), M/s. AstraZeneca USA
	Detail of previous approval	Dewnem 1g Injection,Meeting No 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 Approved	
45	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hi-Med Pharmaceuticals** 208C Sundar industrial estate Raiwind Road Lahore **(000884)**
	Application Form Dy. No / Tracking ID & date of submission	(UDL-LZ7-84H5, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-16,
	The proposed proprietary name / brand name	**Lunet 10mg Tablet**
	Label Claim	Each film coated tablet contains. Dydrogesterone.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20's-As per SRO
	Shelf Life (Unit)	2 YearStore at below 30 degree celcius
	For generic drugs (me-too Status)	Dydrogest 10mg Tablet (OBS pakistan Pvt. Ltd.)
	Pharmacotherapeutic Group of (API)	Genito Urinary system and sex hormones
	Name, address of Manufacturing site:	Skywin Pharmaceuticals.-Plot no. 01 Albadar Industrial Estate Phase II Shaikhupora Road Lahore.-
	The status in reference regulatory authorities	Duphaston 10 mg film-coated tablets (Mylan IRE Healthcare Limited Ireland)
	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 Approved	
46	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**High-Cure Research Laboratories** 19Km Tayyaba industrial Zone Sheikhupura Road Lahore **(000966)**
	Application Form Dy. No / Tracking ID & date of submission	(UBM-LSY-W41U, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-20,
	The proposed proprietary name / brand name	**Itronex Capsule 100mg**
	Label Claim	Each Capsule contains: Itraconazole Immediate release Pellets 22 % w/w equivalent to Itraconazole 100mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4`s-Controlled
	Shelf Life (Unit)	2 YearBelow 30%
	For generic drugs (me-too Status)	Rolac 100mg Capsule Reg No 024491 MS Sami Pharma Karachi
	Pharmacotherapeutic Group of (API)	Anti - Fungal
	Name, address of Manufacturing site:	MS Jinnah Pharmaceuticals Pvt. Ltd-13-KM Lahore Road Multan-
	The status in reference regulatory authorities	SPORANOX 100 mg Capsule By Janssen Ortho LLC, Gurabo, Puerto Rico 00778 (USFDA Approved)
	Detail of previous approval	Reg No 12546 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 Approved	
47	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	(UBA-GEQ-MYUB, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Replay 5mg Tablet**
	Label Claim	Each film coated tablet contains: Tadalafil 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)	Talda 5mg Tablet
	Pharmacotherapeutic Group of (API)	Urologicals
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	358TH meeting approved
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
48	Case Category	New Molecule/Formulation (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dyson Research Laboratories (Pvt.) Ltd** 28-Km Ferozpur Road Lahore **(000559)**
	Application Form Dy. No / Tracking ID & date of submission	(GA7-ZNX-RR5T, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-10-30,
	The proposed proprietary name / brand name	**Suzegin**
	Label Claim	Each film coated tablet contains: Suzetrigine.....50mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C.
	For generic drugs (me-too Status)	Not Applicable.
	Pharmacotherapeutic Group of (API)	Selective blocker of the NaV 1.8 voltage-gated sodium channel.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gansu Haotian Pharmatech Co., Ltd., situated at No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province.
	Detail of stability batches of drug product	Accelerated Stability Studies Batch No: T01, T02 and T03 Real Time Stability Studies Batch No: T01, T02 and T03.

	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC Computerized No: RO-420E42, dated: 24-07-2025.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence: Yes
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated Stability Studies Batch No: SD20230416SUZ, SD20230421SUZ & SD20230426SUZ Real Time / Long Term Stability Studies Batch No: SD20230416SUZ, SD20230421SUZ & SD20230426SUZ.
	The status in reference regulatory authorities	Journavx Tablet 50mg, Applied formulation is registered in United States Food and Drug Administration (USFDA).
	GMP status of the firm	cGMP certificate is granted or valid having Reference No: 222/2024-DRAP (AD-7243533001) dated: 17-12-2024.
	Evidence of approval of manufacturing facility	Grant of letter by DRAP of section/facilities approval vide tracking no: D27-R2B-1W4P dated: 31-07-2025.
	Evaluation Remarks	
	Decision	
	Approved	

49	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	(U8G-8GD-B5PZ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-11,
	The proposed proprietary name / brand name	**MACTHIO**
	Label Claim	Each 2ml ampoule contains: Thiocolchicoside 4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	6's x 2ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 30° C.
	For generic drugs (me-too Status)	Muscoril Injection 4mg/2ml (Searle Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Seraph Pharmaceuticals-Plot No 210, Industrial triangle, Kahuta road, Islamabad-Pakistan-
	The status in reference regulatory authorities	https://medicinali.aifa.gov.it/it/#/it/organizzazione/
	Detail of previous approval	Tiofrel 4mg/2ml Injection, (M-335)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved Approved	
50	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	(U5D-DJ1-726N, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-11,
	The proposed proprietary name / brand name	**FUSE-H Cream**
	Label Claim	Each Gram Contains: Hydrocortisone acetate ..... 10mg Fusidic Acid... ..... 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1,S-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-25C
	For generic drugs (me-too Status)	Fusimax-H 2% Cream, Maxitech pharma, Reg. No. 083733.
	Pharmacotherapeutic Group of (API)	Antibiotic and corticosteroid for topical use.
	Name, address of Manufacturing site:	Aksah Pharmaceuticals Pvt Ltd -Plot NO 47,Street NO NS-10 RCCI Rawat Islamabad-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	333rd DRAP 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 Approved	
51	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nawabsons Laboratories (Pvt) Ltd** Jia bagga, Off Raiwind Road, Lahore **(000493)**
	Application Form Dy. No / Tracking ID & date of submission	(U3Y-AW7-V47J, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-11,
	The proposed proprietary name / brand name	**Nibxime 400mg Capsule**
	Label Claim	Each capsule contains: Cefixime as trihydrate 400mg
	Reference to Finished product specifications	Manufacturer 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:	Bloom Pharmaceuticals Pvt Ltd-Plot No 30 Phase I& II Industrial Estate Hattar -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-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 Approved	
52	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	(U3B-PJH-AZUV, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-24,
	The proposed proprietary name / brand name	**Para Duo**
	Label Claim	Each film-coated tablet contains: Ibuprofen....200mg Paracetamol....500mg (As per Innovators specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x7s,2x7s,4x7s,1x10s,2x10s,3x10s,1x14s,2x14s A 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)	ZENITH CHEMICAL INDUSTRIES (PVT.) LTD
	Name, address of Manufacturing site:	Horizon Healthcare (Pvt)Ltd.-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 Approved	
53	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dyson Research Laboratories (Pvt.) Ltd** 28-Km Ferozpur Road Lahore **(000559)**
	Application Form Dy. No / Tracking ID & date of submission	(TSX-NZ3-H3LV, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Oflomax Ophthalmic Ointment**
	Label Claim	Each gram contains: Ofloxacin.....3mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3.5 gm-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C.
	For generic drugs (me-too Status)	Exocin S.O.P Ophthalmic Ointment by Barrett Hodgson Pakistan (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Quinolone Antimicrobial.
	Name, address of Manufacturing site:	Medevo (Pvt.) Ltd.-Plot no. 94, Sunder Industrial Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Trafloxal eye ointment, applied formulation is registered in Medicines Evaluation Board (Netherland).
	Detail of previous approval	Surgiflox 0.3% Opthalmic Ointment (Ofloxacin), approved in 352 meeting of registration board held on 19 - 20 November, 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 Approved	
54	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well & Well Pharma Pvt.Ltd** Plot No 07, Street S-8, RCCI, Rawat Rawalpindi **(000687)**
	Application Form Dy. No / Tracking ID & date of submission	(TG6-9M3-BQSG, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-01,
	The proposed proprietary name / brand name	**Welltrim-H CREAM**
	Label Claim	Each gm contains: Clotrimazole 10mg Hydrocortisone (as Acetate) 10mg
	Reference to Finished product specifications	British 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)	Hydrozole Cream by GSK
	Pharmacotherapeutic Group of (API)	Data Already Approved in 357 MoM
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Canesten HC Cream HPRA Approved
	Detail of previous approval	Tromatek-H Cream in 357MoM
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
55	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	(TEP-746-QYUL, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-10,
	The proposed proprietary name / brand name	**SILFLO 4MG CAPSULES**
	Label Claim	Each capsule contains: Silodosin.....4mg (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)	Silorap 4mg capsules (Getz Pharma (pvt) Limited)
	Pharmacotherapeutic Group of (API)	alpha-adrenoreceptor antagonists
	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	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 Approved	
56	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(TDJ-2TY-LH8A, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-25,
	The proposed proprietary name / brand name	**Verozen 20mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Vonoprazan as Fumarate.....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 25c
	For generic drugs (me-too Status)	Vonnp 20mg Tablet by Weather Folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anti-ulcerative, Proton pump inhibitor
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Block B, Industrial Estate, Hattar-
	The status in reference regulatory authorities	PMDA JAPAN
	Detail of previous approval	VONOZEN 20mg Tablet, DRB 308
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
57	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**
	Application Form Dy. No / Tracking ID & date of submission	(T29-VP7-ZAWA, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-04,
	The proposed proprietary name / brand name	**REMOX EYE DROPS 5mg/ml**
	Label Claim	Each ml contains: Moxifloxacin as HCl .....5mg (USP Specifications)

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 YearStore between 15°C to 25°C. Protect from sunlight & moisture
	For generic drugs (me-too Status)	Vigamox Eye Drops
	Pharmacotherapeutic Group of (API)	fourth-generation fluoroquinolone antibiotic
	Name, address of Manufacturing site:	M/S Winthrox Pharmaceuticals (Pvt) Ltd-K-291-A, S.I.T.E, Super Highway, Karachi-
	The status in reference regulatory authorities	MOXEZA™ (moxifloxacin hydrochloride ophthalmic solution)
	Detail of previous approval	Moxon Eye drop, Minutes of 339th Drug Registration Board held on 06 -08 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 Approved	
58	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dyson Research Laboratories (Pvt.) Ltd** 28-Km Ferozpur Road Lahore **(000559)**
	Application Form Dy. No / Tracking ID & date of submission	(13X-D7M-9YPB, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Dyzestine Ophthalmic Solution 0.05%**
	Label Claim	Each ml contains: Azelastine HCl 0.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 28C.
	For generic drugs (me-too Status)	Azelast Ophthalmic Solution 0.05% by Innvotek pharmaceuticals.
	Pharmacotherapeutic Group of (API)	Anti-allergic
	Name, address of Manufacturing site:	Medevo (Private) Ltd.-Plot no. 94, Sunder Industrial Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Azelastine hydrochloride 0.5mg/ml Eye Drops by Mylan Products Ltd., applied formulation is registered in Medicines and Healthcare products Regulatory Agency (MHRA).
	Detail of previous approval	Surgilast Ohpthalmic Solution 0.05% (Azelastine HCl), approved in 353 meeting of registration board held on 14 – 15 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	
	Approved Approved	
59	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	(15J-BDQ-HPNQ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Baclo 20mg Tablet**
	Label Claim	Each 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 YearDo not store above 25°C.
	For generic drugs (me-too Status)	Baclin 20mg Tablet by Genome Pharmaceuticals (Pvt.) Ltd..
	Pharmacotherapeutic Group of (API)	gamma-aminobutyric acid (GABA) 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	Rx Baclofen 20mg Tablet by Sanis Health INC
	Detail of previous approval	Baclosol 20mg Tablets, DRB 357
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
60	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**MRCK Pharmaceutical Laboratories (Pvt) Ltd** Plot No. 537-D&E, Sundar Estate, Raiwind Road Lahore **(000753)**
	Application Form Dy. No / Tracking ID & date of submission	(18D-VDE-4RGL, 2026-08-20)

	Detail of Fee Submitted	97200, 2026-06-10,
	The proposed proprietary name / brand name	**Omivenem 500mg Injection**
	Label Claim	Each vial contains: 500 mg Meropenem (as Meropenem trihydrate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30°C
	For generic drugs (me-too Status)	Pfizer Meronem 018543
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Name, address of Manufacturing site:	Fleming Pharmaceuticals-23- Km Lahore-Sheikhpura Road, Lahore.-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	MERO -F INJECTION 500MG 323th 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 Approved	
61	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**MRCK Pharmaceutical Laboratories (Pvt) Ltd** Plot No. 537-D&E, Sundar Estate, Raiwind Road Lahore **(000753)**
	Application Form Dy. No / Tracking ID & date of submission	(1AQ-YSL-NN5E, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-10,
	The proposed proprietary name / brand name	**Omivenem 1gm Injection**
	Label Claim	Each vial contains: 1000 mg Meropenem (as Meropenem trihydrate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Pfizer Meronem Reg#018548
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Name, address of Manufacturing site:	Fleming Pharmaceuticals-23- Km Lahore-Sheikhpura Road, Lahore.-
	The status in reference regulatory authorities	USFDA Approved https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/050706s041lbl.pdf
	Detail of previous approval	Mero-F Inj. 1000 mg - Minutes 323 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 Approved	
62	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	(1B4-GBL-3P3Y, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**STROTMM 2g Sachet**
	Label Claim	Each sachet contains: Strontium Ranelate MS.....2g
	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)	Maqsa 2g Sachet
	Pharmacotherapeutic Group of (API)	Dual Action Bone Agent DABA
	Name, address of Manufacturing site:	Solaris Life Sciences Pvt. Ltd-Plot # 08 Street No. S1 RCCI Industrial Estate Rawat Rawalpindi Pakistan-
	The status in reference regulatory authorities	Registered in UK
	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 Approved	
63	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CSH PHARMACEUTICAL - NORTH (PVT.) LTD** 38 INDUSTRIAL ESTATE HAYATABAD PESHAWAR **(000511)**
	Application Form Dy. No / Tracking ID & date of submission	(1BM-TV5-MXPS, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-17,

	The proposed proprietary name / brand name	**Penum 1g Injection**
	Label Claim	Each vial contains: Meropenem Trihydrate Eq. to Meropenem.....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 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Dew-Max Pharmaceuticals (Pvt) Ltd -PLOT NO 6, STREET NO SS-4, MAIN INDUSTRIAL AREA RAWAT, Islamabad -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-312
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
64	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(1EZ-2UE-2HBY, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**MERONIM 500mg INJECTION**
	Label Claim	Each vial contains: - Meropenem (as trihydrate) .....500mg (Blended with sodium carbonate) (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 Yearbelow 25c
	For generic drugs (me-too Status)	OlVER INJECTION 500mg by GENIX PHARMA
	Pharmacotherapeutic Group of (API)	Carbapenem-Antibiotics
	Name, address of Manufacturing site:	Wallace Pharma Evolutions-Kalalwala stop, 20-KM, Lahore Jaranwala Road Lahore-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Ropen (Meropenem) 500mg injection, 323
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the	

	Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
65	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**MRCK Pharmaceutical Laboratories (Pvt) Ltd** Plot No. 537-D&E, Sundar Estate, Raiwind Road Lahore **(000753)**
	Application Form Dy. No / Tracking ID & date of submission	(1HU-LLN-QQ2T, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-10,
	The proposed proprietary name / brand name	**Omipact 4.5gm Injection**
	Label Claim	Each vial contains: Piperacillin 4 grams (As Piperacillin Sodium) and Tazobactam 0.5 grams (As Tazobactam sodium)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Bosch Pharmaceutical Tanzo Reg#039439
	Pharmacotherapeutic Group of (API)	Penicillin and Beta-Lactam antibiotic
	Name, address of Manufacturing site:	Fleming Pharmaceuticals-23- Km Lahore-Sheikhpura Road, Lahore.-
	The status in reference regulatory authorities	USFDA Approved https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=050684
	Detail of previous approval	Fletazo Inj. 4.5 g - Minutes 323 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 Approved	
66	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(1L5-BB5-3DPD, 2026-08-20)

	Detail of Fee Submitted	97200, 2026-05-21,
	The proposed proprietary name / brand name	**Esovar**
	Label Claim	Each Capsule contains: Enteric Coated Esomeprazole magnesium trihydrate pellets eq. to Esomeprazole....20mg 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)	Nexium 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 Approved	
67	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**wise pharmaceuticals** Plot No 3-A, Street No S-1 RCCI Industrial Estate Rawat. Rawalpindi **(000625)**
	Application Form Dy. No / Tracking ID & date of submission	(1TB-272-DBQX, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-02-26,
	The proposed proprietary name / brand name	**DEXOWIN 30MG CAPSULE**
	Label Claim	Each hard gelatin Capsule contains: DDR Pellets of Dexlansoprazole Eq. to Dexlansoprazole..... 30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's & 3x10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Dexxoo 30mg Capsule Horizon Pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI) WHO ATC Code: A02BC06
	Name, address of Manufacturing site:	M/s Swera Pharmaceuticals-PLOT 27 STREET S4, NATIONAL INDUSTRIAL ZONE, RAWAT INDUSTRIAL ESTATE RAWAT-

	The status in reference regulatory authorities	DEXILANT delayed-release capsules (DEXILANT capsules) Country where sold / registered; USA Manufactured by: Takeda Pharmaceuticals U.S.A
	Detail of previous approval	M-320 (115250)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
68	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	(1X8-JNM-Y3U3, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-11,
	The proposed proprietary name / brand name	**EMPANIC-LT 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	2x7's; 1x14's; 2x14's; 4x7's; 3x10's -As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Celsius
	For generic drugs (me-too Status)	Diampa-LT 25mg/5mg Tablet by M/s Getz Pharma
	Pharmacotherapeutic Group of (API)	Data Already approved in 353 MoM
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Glyxambi 25mg/5mg film-coated tablets , FDA Approved
	Detail of previous approval	Empacal-LT Tablet 25mg/5mg in 353 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 Approved	

69	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	(282-446-TBMV, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-03-17,
	The proposed proprietary name / brand name	**XIPAN Capsules 400mg**
	Label Claim	Each Capsule Contains. Cefixime as Trihydrate----------400mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	generic product
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	SHAWAN PHARMACEUTICALS -Plot No. 37, Road NS 1, National Industrial Zone, RCCI Rawat, Islamabad, Pakistan-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	336th MInutes of meeting helad on 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 Approved	
70	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(2EP-U5P-GH5Z, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-19,
	The proposed proprietary name / brand name	**NIVOMO TABLET 500mg/20mg**
	Label Claim	Each Modified release tablet contains: Naproxen.....500mg (Enteric coated core) Esomeprazole as magnesium trihydrate .....20mg (Immediate released coat)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Yearas required

	For generic drugs (me-too Status)	Glomov 500mg/20mg Tablet by Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	NSAIDS & Proton Pump Inhibitor
	Name, address of Manufacturing site:	WIMITS PHARMACEUTICALS (PVT). LTD - Plot #129 Sundar Industrial Estate,Raiwind road, Lahore -
	The status in reference regulatory authorities	Vimovo 500/20mg modified-release tablet by Grunenthal Ltd, approved by USFDA
	Detail of previous approval	Napsom 20/500 mg Tablet by Wimits Pharmaceuticals Approved in DRB 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
71	Case Category	New Section (Incharge Evaluation Cell)
	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	(9VG-PNA-SJ8T, 2026-04-20)
	Detail of Fee Submitted	75000, 2026-04-08,
	The proposed proprietary name / brand name	**Suzigo 50mg Tablets**
	Label Claim	Each film coated tablet contains: Suzetrigine 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's x 1-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Sodium Channel blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Yibin Hongguang Pharmaceutical Co.,Ltd.
	Detail of stability batches of drug product	Detail of Stability Batches (TR- SZTR -02, TR-SZTR -03, TR- SZTR -04) of three batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	(PE and Comparative Dissolution Profile)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Journavx (Suzetrigine) Tablets of Vertex Pharmaceuticals, Inc (US-FDA)

	GMP status of the firm	Certificate No. 0115-24/2024-DRAP (K), Valid till 25-04-2027
	Evidence of approval of manufacturing facility	DML No. 000707 (Valid till dated 13-06-2026)
	Evaluation Remarks	
	Decision	
	Approved	
72	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	(2V7-LPT-6EJE, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Eric 50mg ODT Tablets**
	Label Claim	Each Orodispersible Tablet contains: Sildenafil as Citrate .....50mg (Innovator Spec's.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 1, 4 x 1, 8 x 1, 12 x 1 or 24 x 1 orodispersible tablet in a box., As per SRO-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30□C. Store in the original package in order to protect from moisture
	For generic drugs (me-too Status)	New Molecule
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic GMP-specificphosphodiesterase (Type V) with vasodilator action;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	MHRA Approved
	Detail of previous approval	RIPPLE ODT 50mg Tablets, DRB 357
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
73	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	(2X6-7XB-D1A5, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Azomay 200mg 5ml Suspension**
	Label Claim	Each reconstituted 5ml contains: Azithromycin .....200mg as dihydrate
	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)	Solithro 200mg5ml DS
	Pharmacotherapeutic Group of (API)	Macrolide class of antibiotics
	Name, address of Manufacturing site:	Solaris Life Sciences Pvt. Ltd.-Plot # 08 Street No. S1 RCCI Industrial Estate Rawat Rawalpindi Pakistan.-
	The status in reference regulatory authorities	USFDA
	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 Approved	
74	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	(338-6HX-9L4A, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Dyna-K 50mg Sachet**
	Label Claim	Each Sachet contains: Diclofenac Potassium..... 50mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s, 30s, As per SRO-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25°C. Store in the original package in order to protect from moisture.
	For generic drugs (me-too Status)	Maxit 50mg sachet by Hilton Pharma (Private) Limited
	Pharmacotherapeutic Group of (API)	NSAID
	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	DYNA-K 50mg Sachet by ASIO HOLDINGS USFDA Approved
	Detail of previous approval	Dpsyl 50mg Sachet, M 357
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
75	Case Category	Contract Manufacturing (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	(38Y-9UB-SLR1, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Nag-Tron Injection**
	Label Claim	Each 4ml Contains: Ondansetron as Hydrochloride dihydrate = 8MG
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year15C to 30C
	For generic drugs (me-too Status)	Onset 8MG/4ml Injection
	Pharmacotherapeutic Group of (API)	Anti-emetics
	Name, address of Manufacturing site:	M/S May & Bakers (Pvt) Ltd-45-km, Dinna Nath, Multan Road, Lahore-
	The status in reference regulatory authorities	FDA
	Detail of previous approval	Proposed Name: Inset 8mg/4ml Injection, Meeting NO.321, Current/Approved Name: Baktron 8mg/4ml Injectiond Name
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
76	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	**Epoch pharma** Plot No 83-85 Sector 15 korangi Industrial Area **(000425)**
	Application Form Dy. No / Tracking ID & date of submission	(3AW-SX3-LMUV, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-03-26,
	The proposed proprietary name / brand name	**Kilbac Injection 2gm**
	Label Claim	Each vial contains: Cefoperazone Sodium eq. to Cefoperazone.....1000mg + Sulbactam Sodium eq. to Sulbactam.....1000mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Sulzone 2Gm Injection by Biocare Pharmaceutica , 807-Shadman-I, Lahore,
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE Super Highway, Phase-II, Karachi-
	The status in reference regulatory authorities	Cefobid Injection Pfizer Pvt. Ltd. approved by FDA
	Detail of previous approval	Cefo-Qph 2gm Injection approved in 352 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 Approved	
77	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(3AZ-NHT-A8XV, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-21,
	The proposed proprietary name / brand name	**Dexole**
	Label Claim	Each Capsule contains: Dexlansoprazole (as Dual delayed release pellets)...60mg (As Per Innovators Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's -As per SRO
	Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	Razodex 60mg 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 320th 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 Approved	
78	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)**
	Application Form Dy. No / Tracking ID & date of submission	(3JP-RU8-GHTG, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-24,
	The proposed proprietary name / brand name	**Zolchem-4mg/5ml Infusion**
	Label Claim	Each 5ml vial contains: Zoledronic acid as monohydrate.....4mg (Innovator Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 YearNMT 25 degree centigrade
	For generic drugs (me-too Status)	M/s Merixil Pharma Islamabad
	Pharmacotherapeutic Group of (API)	Bisphosphonates
	Name, address of Manufacturing site:	Biogen Life Sciences-8 km Chakbeli, Road Rawat.-
	The status in reference regulatory authorities	ZOMETA 4MG/5ML CONCENTRATE FOR SOLUTION FOR INFUSION MHRA Approved
	Detail of previous approval	Gen-Zole 4mg/5ml concentrate for solution for infusion, 353 minutes of meetings
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

	Approved	
79	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**MRCK Pharmaceutical Laboratories (Pvt) Ltd** Plot No. 537-D&E, Sundar Estate, Raiwind Road Lahore **(000753)**
	Application Form Dy. No / Tracking ID & date of submission	(43J-5NY-GL7G, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-22,
	The proposed proprietary name / brand name	**Mrkstron 4mg/5ml Syrup**
	Label Claim	Each 5ml contains; Ondansetron hydrochloride dihydrate eq. to Ondansetron.....4mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30ml and 60ml-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Onsetron 4mg/5ml Reg. No. 109747 M/s Dyson Research Laboratories Lahore
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists
	Name, address of Manufacturing site:	M/s Himark Laboratories(Pvt),Ltd-Plot No.37 .A Sundar Industrial estate Lahore-
	The status in reference regulatory authorities	ONDANSETRON 4MG/5ML SYRUP MHRA Approved.
	Detail of previous approval	333-RB Ondansetron Syrup 517-520
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
80	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	(4GV-7AQ-1H1Q, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Ferritose 500mg/10ml Inj**
	Label Claim	Each ml Contains: Ferric Carboxymaltose Equivalent to Elemental Iron..... 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1,S-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-25C

	For generic drugs (me-too Status)	IZER (Ferric carboxymaltose) 500mg/10ml Injection M/S Pharmasol Pvt Ltd Registration number 115449
	Pharmacotherapeutic Group of (API)	iron replacement product
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot NO. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore. -
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Medifer50mg/1ml Injection DRAP 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 Approved	
81	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	(4P4-X33-UQ36, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-01-28,
	The proposed proprietary name / brand name	**RUPETRA**
	Label Claim	Each tablet contains: Rupatadine (as fumarate)..... 10mg
	Reference to Finished product specifications	As per Innovators Specification
	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)	N/A
	Pharmacotherapeutic Group of (API)	Vasudha Pharma Chem Limited Unit-II,
	Name, address of Manufacturing site:	Genix Pharma (Pvt)Ltd.-44, 45B, KORANGI CREEK ROAD, Karachi.-
	The status in reference regulatory authorities	Generfarma SL, Spain (Rupatadine)
	Detail of previous approval	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 Approved	
82	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT **(000941)**
	Application Form Dy. No / Tracking ID & date of submission	(4UA-MWX-42XR, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-30,
	The proposed proprietary name / brand name	**SWETIN TABLETS**
	Label Claim	Each film coated tablet contains: Ebastine 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Ebastine Tablets Highnoon Laboratories Limited, Pakistan
	Pharmacotherapeutic Group of (API)	Other antihistamines for systemic use
	Name, address of Manufacturing site:	M/s Pine Pharmaceuticals-Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.-
	The status in reference regulatory authorities	Kestine film-coated tablets 20 mg Netherland
	Detail of previous approval	M-330
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
83	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**
	Application Form Dy. No / Tracking ID & date of submission	(4V3-2DV-VWXT, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-04,
	The proposed proprietary name / brand name	**TORACID-D EYE DROPS 3MG+1MG/ML**
	Label Claim	Each ml of Suspension Contains: Tobramycin.....3mg + Dexamethasone.....1mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5ml-As per SRO

	Shelf Life (Unit)	2 YearStore between 15°C to 25°C. Protect from sunlight& moisture
	For generic drugs (me-too Status)	TOBRADEX SUSPENSION
	Pharmacotherapeutic Group of (API)	Combination medication that pairs an aminoglycoside antibiotic with a corticosteroid
	Name, address of Manufacturing site:	M/S Winthrox Pharmaceuticals (Pvt) Ltd-K-291-A, S.I.T.E, Super Highway, Karachi-
	The status in reference regulatory authorities	TOBRADEX
	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 Approved	
84	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(5YY-QQ6-BBV2, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-21,
	The proposed proprietary name / brand name	**Esovar**
	Label Claim	Each Vial Contains: Esomeprazole Sodium eq. to Esomeprazole.....40mg BP Specifications
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's -As per SRO
	Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	NEXUM 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	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 Approved	
85	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(7DY-8YE-6SEE, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**Citkon 1000mg/4ml Injection**
	Label Claim	Each Ampoule (4mL) Contains: Citicoline as Sodium Salt (USP).....1000mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25c
	For generic drugs (me-too Status)	Coli Wan Injection by Swan Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anti-Parkinson
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	ANSM France
	Detail of previous approval	C-kolin, DRB 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 Approved	
86	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(7XZ-A3D-Y2UD, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**Forbud 400/12mcg DPI Capsule**
	Label Claim	Each capsule contains: Budesonide.....400mcg Formoterol Fumarate Dihydrate...12mcg Each delivered dose contains: Budesonide....320mcg Formoterol Fumarate Dihydrate.....9mcg (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 YearStore Below 25c
	For generic drugs (me-too Status)	Venticort Rotacaps 400mg + 12mcg Highnoon Labs
	Pharmacotherapeutic Group of (API)	Long-Acting Beta Agonists
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot no. 69/1, Block-B, Phase I-II, Industrial Estate, Hattar-
	The status in reference regulatory authorities	UK MHRA Approved
	Detail of previous approval	Combrain, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
87	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(8YD-ALW-LZWJ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-25,
	The proposed proprietary name / brand name	**Levowel 25mg Tablet**
	Label Claim	Each Uncoated Tablet Contains: Levosulpride.....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 Yearbelow 25c
	For generic drugs (me-too Status)	Hi Pride Tablet by Bloom Pharma
	Pharmacotherapeutic Group of (API)	Tranquillizers
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat. -
	The status in reference regulatory authorities	AIFA ITALY
	Detail of previous approval	Sulrid 25mg Tablet, DRB 353
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved Approved	
88	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(9RQ-M51-SNPR, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**ONDANZ 4mg/2ml Injection**
	Label Claim	Each Ampoule (2mL) Contains: Ondansetron as Hydrochloride Dihydrate.....4mg (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 Yearbelow 25c
	For generic drugs (me-too Status)	Doston Injection by Vision Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Serotonin 5-Ht3 Receptor Antagonists
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Block B, Industrial Estate, Hattar-
	The status in reference regulatory authorities	UK MHRA
	Detail of previous approval	Ondanz 4mg/2ml Injection, DRB 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 Approved	
89	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(A27-VPP-738V, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-25,
	The proposed proprietary name / brand name	**Levowel 50mg Tablet**
	Label Claim	Each Uncoated Tablet Contains: Levosulpride.....50mg (Product complies Innovator's Specs)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 25c
	For generic drugs (me-too Status)	Hi Pride Tablet by Bloom Pharma
	Pharmacotherapeutic Group of (API)	Tranquillizers
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat. -
	The status in reference regulatory authorities	AIFA ITALY
	Detail of previous approval	Sulrid 50mg Tablet, DRB 353
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
90	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	**Shaigan Pharmaceuticals (Pvt) Ltd** 14Km Adyala Road Post office Dahgal Rawalpindi **(000333)**
	Application Form Dy. No / Tracking ID & date of submission	(LQH-P8S-MBA1, 2026-04-07)
	Detail of Fee Submitted	75000, 2026-01-02,
	The proposed proprietary name / brand name	**SUZETRIN 50mg TABLETS**
	Label Claim	Each Film Coated tablet contains: Suzetrigine ...50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	(10x3's)-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C.
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Non-opioid Analgesic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CHONGQING ASINCAN BIOTECH CO., LTD.
	Detail of stability batches of drug product	238NS02, 238NS03, 238NS04
	Documents for the procurement of API with approval from DRAP (in case of Import)	04-06-2025
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Journavx 50mg Tablet (Vertex Pharmaceuticals Boston, USA)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	ASC030-230301, ASC030-230302, ASC030-230303
	The status in reference regulatory authorities	NA
	GMP status of the firm	20 February, 2024
	Evidence of approval of manufacturing facility	01 July, 1993
	Evaluation Remarks	

	Export facilitaiton	
	Decision	
	Approved	
91	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(AZ6-1PE-V7UR, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-21,
	The proposed proprietary name / brand name	**Well-Mox**
	Label Claim	Each film coated tablet contains: Moxifloxacin hydrochloride 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 400mg Tablet of M/s Getz Pharma (Reg.#047117
	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 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 Approved	
92	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(B1V-YBJ-H9R3, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-21,
	The proposed proprietary name / brand name	**PT-40**
	Label Claim	Each Enteric coated tablet contains: Pantoprazole Sodium (as Sodium Sesquihydrate) = 40 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's & 28's -As per SRO

	Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	Protium 40mg Tablet
	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 316th meeting of Registration Board (15-18 March, 2022)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
93	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(BSM-SV8-3WPX, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-21,
	The proposed proprietary name / brand name	**Pirocam**
	Label Claim	Each tablet contains: Piroxicam beta Cyclodextrin eq. to Piroxicam...20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20's -As per SRO
	Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	Achway Tablets of M/s Getz Pharma (Reg.#047355)
	Pharmacotherapeutic Group of (API)	nonsteroidal anti-inflammatory drug (NSAID)
	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 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 Approved	
94	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(BUU-ZB9-L6WZ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**MERONIM 1000mg INJECTION**
	Label Claim	Each vial contains: - Meropenem (as trihydrate) .....1000mg (Blended with sodium carbonate) (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 Yearbelow 25c
	For generic drugs (me-too Status)	OlVER INJECTION 1000mg by GENIX PHARMA
	Pharmacotherapeutic Group of (API)	Carbapenem-Antibiotics
	Name, address of Manufacturing site:	Wallace Pharma Evolutions-Kalalwala stop, 20-KM, Lahore Jaranwala Road Lahore-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Ropen 1g Injection, 323
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
95	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(EMP-227-1NDB, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-25,
	The proposed proprietary name / brand name	**Prostone 100mg Tablet**
	Label Claim	Each Uncoated Tablet contains: Progesterone (USP).....100mg (Product Complies Innovator's Specs)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 25c
	For generic drugs (me-too Status)	Prostone 100mg Tablet by Weather Folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Progestins
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Block B, Industrial Estate, Hattar-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Prostone 100mg Tablet, DRB 344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
96	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(GN3-RDJ-6AJA, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-21,
	The proposed proprietary name / brand name	**Thio-well**
	Label Claim	Each Capsule Contains: Thiocolchicoside 4mg
	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)	Muscoril 4 mg cap by M/s Sanofi-aventis Pakistan Ltd..., Reg. No. 015502
	Pharmacotherapeutic Group of (API)	Analgesic and Anti-inflammatory
	Name, address of Manufacturing site:	Variant Pharmaceuticals Pvt Ltd.-Plot no 5 M2 Pharmazone Sharqpur lahore-Road.-
	The status in reference regulatory authorities	ANSM FRANCE
	Detail of previous approval	Minutes of 329th 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 Approved	
97	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(JBT-5DV-W5Q4, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-21,
	The proposed proprietary name / brand name	**Varipride**
	Label Claim	Each tablet contains Levosulpiride 25mg
	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)	Syconor Tablet 25mg, Opal Laboratories, Reg. No. 096116.
	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 Approved	
98	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(LSW-8ZL-T5W3, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**Nerista 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 YearStore Below 25c
	For generic drugs (me-too Status)	Postpon-M Tablet by OBS Pharma
	Pharmacotherapeutic Group of (API)	Progestins
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Norista, 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 Approved	
99	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(LT8-B4Q-HV8W, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**ONDANZ 4mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Ondansetron as Hydrochloride Dihydrate (USP).....4mg (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 Yearbelow 25c
	For generic drugs (me-too Status)	Oniron 4mg Tablet by Genome Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Serotonin 5-Ht3 Receptor Antagonists
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Block B, Industrial Estate, Hattar-
	The status in reference regulatory authorities	UK MHRA
	Detail of previous approval	Ondanz 8mg Tablet, 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 Approved	
100	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(N3X-EUE-TVXH, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**ONDANZ 8mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Ondansetron as Hydrochloride Dihydrate (USP).....8mg (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 Yearbelow 25c
	For generic drugs (me-too Status)	Oniron 8mg Tablet by Genome Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Serotonin 5-Ht3 Receptor Antagonists
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Block B, Industrial Estate, Hattar-
	The status in reference regulatory authorities	UK MHRA
	Detail of previous approval	Ondanz 8mg Tablet, 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 Approved	
101	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	(58L-D8P-J42D, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Paroset 20mg Tablets**
	Label Claim	Each film coated tablet contains: Paroxetine HCl equivalent to Paroxetine.....20mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	10s, 30s, As per SRO-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25 °C.
	For generic drugs (me-too Status)	Paraxyl 20 mg Tablets by CCL Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitor (SSRI)
	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	Paroxetine 20mg Tablets by Apotex Pharmaceutical corporation USFDA approved
	Detail of previous approval	Proxet 20mg Film Coated Tablets, DRB 357
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
102	Case Category	Contract Manufacturing (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	(5AM-WW3-38LX, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**VANCOCARE 1g**
	Label Claim	Each vial Contains: Vancomycin Hydrochloride eq. to Vancomycin = 1 G
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year15C to 30C
	For generic drugs (me-too Status)	Vancomycin Injection 1g by M/s Abbott Pharma
	Pharmacotherapeutic Group of (API)	Antibacterials
	Name, address of Manufacturing site:	M/s May & Baker (Pvt) Ltd-45-Km, Dina Nath, Multan Road, Lahore -
	The status in reference regulatory authorities	FDA
	Detail of previous approval	Myocin 1g Dry Powder vial I.V , 324th 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 Approved	
103	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	(5DU-MPG-31ZM, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-11,
	The proposed proprietary name / brand name	**EMPANIC 25mg TABLET**
	Label Claim	Each Film Coated tablet contains: Empagliflozin 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Celsius
	For generic drugs (me-too Status)	Empozin 25mg Tablet by M/s Macter International
	Pharmacotherapeutic Group of (API)	Data Already approved in 352 MoM
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Jardiance Tablet 25mg , FDA Approved
	Detail of previous approval	Empacal Tablet 25mg in 352 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 Approved	
104	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**
	Application Form Dy. No / Tracking ID & date of submission	(5JW-Q6X-93A6, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-04,
	The proposed proprietary name / brand name	**ONDESTY 8MG TABLET**
	Label Claim	Each film coated tablet contains: Ondansetron Hydrochloride (as Dihydrate) equivalent to Ondansetron... 8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO/DPC-As per SRO

	Shelf Life (Unit)	2 YearStore below 25°C. Protect from sunlight& moisture
	For generic drugs (me-too Status)	Onsetron Tablets 8mg
	Pharmacotherapeutic Group of (API)	serotonin 5-HT3 receptor antagonist
	Name, address of Manufacturing site:	M/S Winthrox Pharmaceuticals (Pvt) Ltd-K-291-A, S.I.T.E, Super Highway, Karachi-
	The status in reference regulatory authorities	ZOFRAN Tablets
	Detail of previous approval	Ondesty 8 mg Tablet, Minutes of 336 Meeting of registration board held on 4th - 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 Approved	
105	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	(5JZ-P6D-X5PP, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Neomet Vaginal tablet**
	Label Claim	Each tablet contains: Metronidazole.....500mg Neomycin Sulphate.....65000IU Nystatin ..... 100000IU (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO, 10's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C. Do not freeze. Protect from excessive heat and moisture, which can cause the tablets to melt or degrade.
	For generic drugs (me-too Status)	Megyne Vaginal Tablets by Nabiqasim Industries (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antibacterial & Antifungal agent for Vaginal Infections
	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	Tergynan Tablets (ANSM France Approved)
	Detail of previous approval	Numet Tablets, DRB 357
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to	

	submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
106	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Jinnah Pharmaceuticals Pvt Ltd** 13 Km Lahore Road Multan **(000578)**
	Application Form Dy. No / Tracking ID & date of submission	(5PY-BPS-TVWR, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-20,
	The proposed proprietary name / brand name	**DOVIA TABLET 10MG**
	Label Claim	EACH FILM COATED TABLET CONTAINS: DYDROGESTERONE 10 MG
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2`s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30%
	For generic drugs (me-too Status)	Dydrogest 10mg Tablet. OBS Pakistan (Pvt) Ltd., C-14 Mangopir Road SITE Karachi. , Karachi.
	Pharmacotherapeutic Group of (API)	Progestagens (Progestins
	Name, address of Manufacturing site:	SKYWIN PHARMACEUTICALS PVT LDT.- PLOT NO 1/A1 BADAR INDUSTRIAL ESTATE PHASE –II 18-KM SHEIKHUPURA ROAD LAHORE.-
	The status in reference regulatory authorities	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	Dydrosky Tab 10mg Reg No 121773 approved in 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 Approved	
107	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More.

		(001029)
	Application Form Dy. No / Tracking ID & date of submission	(PGA-AVE-DTVH, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-25,
	The proposed proprietary name / brand name	**Biltex 10mg Orodispersible Tablet**
	Label Claim	Each Oro-dispersible 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 25c
	For generic drugs (me-too Status)	Orodispersible Tablet Bilix 10 mg by M/s AGP Limited
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat. -
	The status in reference regulatory authorities	UK MHRA
	Detail of previous approval	BILTEX 10mg Orodispersible Tablet, DRB 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 Approved	
108	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(PJM-EPG-N3E8, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**Citkon 250mg/2ml Injection**
	Label Claim	Each Ampoule (2mL) Contains: Citicoline as Sodium Salt (USP).....250Mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25c
	For generic drugs (me-too Status)	Coli Wan Injection by Swan Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anti-Parkinson
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	ANSM France

	Detail of previous approval	C-kolin, DRB 347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
109	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well & Well Pharma Pvt.Ltd** Plot No 07, Street S-8, RCCI, Rawat Rawalpindi **(000687)**
	Application Form Dy. No / Tracking ID & date of submission	(QUT-G7S-ESYV, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-01,
	The proposed proprietary name / brand name	**CLOBETA CREAM**
	Label Claim	Each gram contains: Clotrimazole 10mg Betamethasone (as Dipropionate). 0.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10g; 15g; 20g; 30g-As per SRO
	Shelf Life (Unit)	2 YearStore below 30c
	For generic drugs (me-too Status)	Lotricort Cream By M/s Dermagen Pharma Pakistan
	Pharmacotherapeutic Group of (API)	Data Already Approved in 352 MoM
	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 (MHRA Approved)
	Detail of previous approval	Betacline-C Cream in 352 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 Approved	
110	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**

	Application Form Dy. No / Tracking ID & date of submission	(S8R-7BM-LD5N, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**ONDANZ 4mg/5ML SYRUP**
	Label Claim	Each 5ml Contains: Ondansetron as Ondansetron Hydrochloride Dihydrate (USP).....4mg (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 Yearbelow 25c
	For generic drugs (me-too Status)	Ondan syrup 4mg/5ml by Bio-mark pharmaceutical
	Pharmacotherapeutic Group of (API)	Serotonin 5-Ht3 Receptor Antagonists
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Block B, Industrial Estate, Hattar-
	The status in reference regulatory authorities	UK MHRA
	Detail of previous approval	ONDANZ 4mg/5ml Syrup, 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 Approved	
111	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(SS8-SX9-GH5E, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-25,
	The proposed proprietary name / brand name	**Verozen 10mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Vonoprazan as Fumarate.....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 25c
	For generic drugs (me-too Status)	Vonnp 10mg Tablet by Weather Folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anti-ulcerative, Proton pump inhibitor
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Block B, Industrial Estate, Hattar-
	The status in reference regulatory authorities	PMDA JAPAN

	Detail of previous approval	VONOZEN 10mg Tablet, DRB 308
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
112	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(6BV-14L-YJBM, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-05,
	The proposed proprietary name / brand name	**Mirotar Tablet 15mg**
	Label Claim	Each Film Coated Tablet Contains: Mirogabalin Besylate eq.to Mirogabalin 15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	3 Yearas required
	For generic drugs (me-too Status)	Mirogab 15mg Tablet by Wimits
	Pharmacotherapeutic Group of (API)	Gabapentinoid medication primarily used for the treatment of neuropathic pain
	Name, address of Manufacturing site:	WIMITS PHARMACEUTICALS (PVT). LTD - Sunder Industrial Estate Lahore, Pakistan-
	The status in reference regulatory authorities	Tarlige Tablets by Daiichi Sankyo PMDA Approved
	Detail of previous approval	Mirogab 15mg Tablet Approved in DRB 344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
113	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**gulfpharmaceuticals** Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. **(000750)**

	Application Form Dy. No / Tracking ID & date of submission	(6E9-45N-VSUS, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-09,
	The proposed proprietary name / brand name	**Samper**
	Label Claim	Each Film coated tablet contains Paracetamol 325mg, Tramadol 37.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore belove 30C
	For generic drugs (me-too Status)	Tonoflex-p tablet of Sami
	Pharmacotherapeutic Group of (API)	Opioids in combination with non-opioid analgesics
	Name, address of Manufacturing site:	Biogen Pharmaceuticals-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Ultracet® Tablet USFDA
	Detail of previous approval	Paradol D tablet in 335th meeting of RB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
114	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(6L3-UW7-1ETV, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Norterone 5mg Tablet**
	Label Claim	Each Tablet contains: Norethisterone.....5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Primolut-N Tablet of M/s OBS Pharma Pvt. LTd.
	Pharmacotherapeutic Group of (API)	Norethisterone, also known as norethindrone, is a synthetic progestational hormone belonging to the 19-nortestosterone-derived class of progestins.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals Pvt. Ltd.-Plot # 01, AL Badar Idustrial Estate Phase II, Sheikhupura Road, Sheikhupura Sheikhupura-

	The status in reference regulatory authorities	Primolut N Tablet 5mg of M/s Bayer plc, 400 South Oak Way, Reading, Berkshire, RG2 6AD (MHRA Approved)
	Detail of previous approval	Just-N 5mg Tablet - 347th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
115	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	(6Y9-JV6-AA4D, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Replay 10mg Tablet**
	Label Claim	Tadalafil 10mg
	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)	Talda 10mg Tablet Medizan
	Pharmacotherapeutic Group of (API)	Urologicals
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	358TH meeting approved
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
116	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	(737-A28-GXYU, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Styramin 15g Sachet**
	Label Claim	Each sachet contains: Calcium polystyrene sulfonate 15g
	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)	Kinelane 15gm sachet
	Pharmacotherapeutic Group of (API)	cation-exchange resin or potassium-removing agent
	Name, address of Manufacturing site:	Solaris Life Sciences Pvt. Ltd-Plot # 08 Street No. S1 RCCI Industrial Estate Rawat Rawalpindi Pakistan.-
	The status in reference regulatory authorities	Registered in UK
	Detail of previous approval	MVA-U5B-BXWW
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
117	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**
	Application Form Dy. No / Tracking ID & date of submission	(7M3-E66-YXLN, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-19,
	The proposed proprietary name / brand name	**ONDESTY SYRUP 4mg/5mL**
	Label Claim	Each 5ml contains: Ondansetron Hydrochloride Dihydrate eq. to Ondansetron.....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 YearStore between 15°C to 25°C. Protect from sunlight & moisture
	For generic drugs (me-too Status)	Onseron Syrup
	Pharmacotherapeutic Group of (API)	5-HT3 receptor antagonists
	Name, address of Manufacturing site:	M/S Winthrox Pharmaceuticals (Pvt) Ltd-K-291-A, S.I.T.E, Super Highway, Karachi-
	The status in reference regulatory authorities	ZOFRAN ORAL SOLUTION

	Detail of previous approval	Ondesty 4mg/5ml-- Minutes 331 Drug Registration Board held on 31 Oct - 02 Nov 2023
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
118	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)**
	Application Form Dy. No / Tracking ID & date of submission	(7GL-4XN-NGHX, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-08,
	The proposed proprietary name / brand name	**EMPEG-ML 5mg + 2.5mg + 1000mg XR TABLET**
	Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....5mg Linagliptin.....2.5mg (As immediate release core) Metformin Hydrochloride*.....1000mg (As extended release core) (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 25c
	For generic drugs (me-too Status)	Ezliz XR Tablet by Welmark Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors Dipeptidyl peptidase-4 (DPP-4) inhibitors Biguanide
	Name, address of Manufacturing site:	Welmark Pharmaceuticals-Plot No. 122, Block - B, Phase V, Industrial Estate Hattar.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	EMPEG-ML XR TABLET, DRB 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	

	Approved	
119	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Panacea Pharmaceuticals** plot No 04,Street S-6 National industrial Zone RCCI rawat islamabad **(000600)**
	Application Form Dy. No / Tracking ID & date of submission	(7QB-9DV-16MX, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-25,
	The proposed proprietary name / brand name	**Vonit 20mg Tablets**
	Label Claim	Each Film Coated Tablet Contains: Vonoprazan Fumarate eq.to Vonoprazan ..... 20mg. (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 YearBelow 30C
	For generic drugs (me-too Status)	Vonozan 20mg Tablet (Getz Pharma)
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Name, address of Manufacturing site:	M/s Pine Pharmaceuticals-Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.-
	The status in reference regulatory authorities	PMDA Japan Approved
	Detail of previous approval	Vonoprazon 20mg Tablet, 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 Approved	
120	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	(7XE-QUP-LJDH, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-20,
	The proposed proprietary name / brand name	**Nasbul Injection 10 mg/ml**
	Label Claim	Each ml ampoule contains: Nalbuphine hydrochloride.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Celcius
	For generic drugs (me-too Status)	Nale 10 mg/ml Injection
	Pharmacotherapeutic Group of (API)	Opioid agonist-antagonist

	Name, address of Manufacturing site:	Islam Pharmaceuticals -7-Km, Pasrur Road, Sialkot. -
	The status in reference regulatory authorities	Nalbuphine HCl Injection
	Detail of previous approval	Nalphine 10 mg/ml Injection, M-317
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
121	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	(7XM-1H5-X4BE, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-04,
	The proposed proprietary name / brand name	**Upagen 15mg XR Tablet**
	Label Claim	Each Film coated tablet Extended-release tablet contains Upadacitinib Hemihydrate eq. 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 YearStore in cool and dry place. Protect from direct heat and light.
	For generic drugs (me-too Status)	Wimits Pharmaceuticals Pvt. Ltd Brand name: Upacit XR Tablet
	Pharmacotherapeutic Group of (API)	Janus kinase (JAK) inhibitor
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot No. 129 Sundar industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Registration Status: Registered in US-FDA NDA: 211675 Brand Name: RINVOQ 15mg XR Tablets Company: ABBVIE Inc. Address: 1 N. Waukegan Road North Chicago, Illinois 60064United States
	Detail of previous approval	Upacit 15mg XR Tablet, 344 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 Approved	
122	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hisun Pharmaceutical Industries** 37-A, R-2 Industrial Estate Gadoon, Amazi **(000624)**
	Application Form Dy. No / Tracking ID & date of submission	(87X-YVG-APY4, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-09,
	The proposed proprietary name / brand name	**Ondensen Tablet 8mg**
	Label Claim	Each film coated tablet contains: Ondansetron Hydrochloride (as Dihydrate) equivalent to Ondansetron... 8mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Onsetron Tablets 8mg 062816 by Dyson Research Laboratories (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Antiemetic
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE Super Highway, Phase-II, Karachi-
	The status in reference regulatory authorities	Ondansetron Tablet Approved By Health Canada
	Detail of previous approval	Ondesty 8mg Tablet Approved in 336th Meeting DRB dated 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 Approved	
123	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	(8A8-JSP-E6GH, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Caverda 10mg Tablets**
	Label Claim	Each filmcoated tablet contains: Vardenafil Hydrochloride eq. to Vardenafil 10mg
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30°C
	For generic drugs (me-too Status)	132425 varda 10mg tablets
	Pharmacotherapeutic Group of (API)	Urologicals Drugs used in erectile dysfunction ATC code: G04BE09. Vardenafil is an oral therapy for the improvement of erectile function in men with erectile dysfunction
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-Plot No 313 Industrial Triangle Kahuta road Islamabad-
	The status in reference regulatory authorities	Bayer Healthcare Bayer Pharmaceutical Corporation 400 Morgan Lane West Haven CT 06516 Made in Germany LEVITRA Vardenafil HCl tablets for oral use Tablets: 2.5 mg 5 mg 10 mg 20 mg Initial U S Approval: 2003
	Detail of previous approval	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 Approved	
124	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	(8DQ-8BQ-ETXV, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-11,
	The proposed proprietary name / brand name	**Pateye 0.7% Ophthalmic Solution**
	Label Claim	Each ml contains: Olopatadine Hydrochloride eq. to Olopatadine ..... 7mg (United States Pharmacopeia)
	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)	Olopharm Ophthalmic Solution by Epharm Laboratories
	Pharmacotherapeutic Group of (API)	Selective H1-receptor antagonists
	Name, address of Manufacturing site:	OPTIMUS LABORATORIES (PVT.) LTD.-PLOT NO.62, BHALWAL INDUSTRIAL ESTATE, BHALWAL, DIST. SARGODHA-
	The status in reference regulatory authorities	FDA approved
	Detail of previous approval	354th 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 Approved	
125	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Bloom Pharmaceuticals (Pvt) Ltd.** Plot No. 30, Phase I & II, Industrial Estate, Hattar **(000374)**
	Application Form Dy. No / Tracking ID & date of submission	(8GM-EZ6-SH7W, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-15,
	The proposed proprietary name / brand name	**Esonex Tablet**
	Label Claim	Each Modified release Tablet contains: Naproxen .....500mg (as Enteric Coated Core) Esomeprazole as Magnesium Trihydrate .....20mg (as Immediate Release Coat)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s-As per SRO,28s-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:	WnsFeild Pharmaceuticals-Plot #122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-324
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
126	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(8QH-JMJ-TBL7, 2026-08-20)

	Detail of Fee Submitted	97200, 2026-05-19,
	The proposed proprietary name / brand name	**NIVOMO 375mg/20mg Tablets**
	Label Claim	Each Modified release tablet contains: Naproxen.....375mg (Enteric coated core) Esomeprazole as magnesium trihydrate .....20mg (Immediate released coat)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 2x7's, 3x7's, 10's, 2x10's, 3x10's and As per SRO -As per SRO
	Shelf Life (Unit)	2 YearAs required
	For generic drugs (me-too Status)	Glomov 375mg/20mg Tablet by Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	As previously submitted
	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	Vimovo 375/20mg modified-release tablet by Grunenthal Ltd, approved by USFDA.
	Detail of previous approval	Napsom 20/375 mg 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 Approved	
127	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**
	Application Form Dy. No / Tracking ID & date of submission	(8RG-GRS-HR4B, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-04,
	The proposed proprietary name / brand name	**OSTOLEC INJECTION 30MG/ML**
	Label Claim	Each ml of ampoule contains: Ketorolac Tromethamine.....30mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 YearStore between 15°C to 25°C. Protect from sunlight& moisture
	For generic drugs (me-too Status)	Toradol Injection
	Pharmacotherapeutic Group of (API)	Nonsteroidal anti-inflammatory (NSAID)

	Name, address of Manufacturing site:	M/S Winthrox Pharmaceuticals (Pvt) Ltd-K-291-A, S.I.T.E, Super Highway, Karachi-
	The status in reference regulatory authorities	Ketorolac Injection Manufactured by Pfizer
	Detail of previous approval	Qetotrom Injection; Minutes of 357th Meeting of Registration held on 21st April 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	
	Approved Approved	
128	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**
	Application Form Dy. No / Tracking ID & date of submission	(9QR-JL4-E8Y9, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-04,
	The proposed proprietary name / brand name	**TORACID EYE DROPS 3mg/ml**
	Label Claim	Each ml of solution contains: Tobramycin 3mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 YearStore between 15°C to 25°C.
	For generic drugs (me-too Status)	TOBREX OPHTHALMIC SOLUTION
	Pharmacotherapeutic Group of (API)	Aminoglycoside antibiotic
	Name, address of Manufacturing site:	M/S Winthrox Pharmaceuticals (Pvt) Ltd-K-291-A, S.I.T.E, Super Highway, Karachi-
	The status in reference regulatory authorities	TOBREX® (tobramycin ophthalmic solution) 0.3%
	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 Approved	

129	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Zamko Pharmaceuticals (Pvt) Ltd.** 641-A, Sunder Industrial Estate, Raiwind Road, **(000890)**
	Application Form Dy. No / Tracking ID & date of submission	(9QW-E6Z-6Z39, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-01,
	The proposed proprietary name / brand name	**EZONEP 500mg/20mg DR Tablet**
	Label Claim	Each Modified release Tablet contains: Naproxen .....500mg (as Enteric Coated Core) Esomeprazole as Magnesium Trihydrate .....20mg (as Immediate Release Coat) (As per Innovators Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 25c
	For generic drugs (me-too Status)	Glomov Tablet by Global Pharma
	Pharmacotherapeutic Group of (API)	Nonnarcotic analgesic, antipyretic, anti-inflammatory plus Proton Pump Inhibitor
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat. -
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Eenox 20mg/500mg Tablet, DRB 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 Approved	
130	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	(9ZX-WB3-584R, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Caverda 5mg Tablets**
	Label Claim	Each filmcoated tablet contains: Vardenafil Hydrochloride eq. to Vardenafil 5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30°C

	For generic drugs (me-too Status)	varda 5mg tablets 132424
	Pharmacotherapeutic Group of (API)	Urologicals Drugs used in erectile dysfunction ATC code: G04BE09. Vardenafil is an oral therapy for the improvement of erectile function in men with erectile dysfunction
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-Plot No 313 Industrial Triangle Kahuta road Islamabad-
	The status in reference regulatory authorities	Bayer Healthcare Bayer Pharmaceutical Corporation 400 Morgan Lane West Haven CT 06516 Made in Germany LEVITRA Vardenafil HCl tablets for oral use Tablets: 2.5 mg 5 mg 10 mg 20 mg Initial U S Approval: 2003
	Detail of previous approval	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 Approved	
131	Case Category	Export Facilitation (Incharge Evaluation Cell)
	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	(MJN-QE9-A38B, 2026-07-06)
	Detail of Fee Submitted	75000, 2026-06-19,
	The proposed proprietary name / brand name	**SUZEE**
	Label Claim	Each Film coated tablet contains: Suzetrigine.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	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)	NA
	Pharmacotherapeutic Group of (API)	Halolife (Xiamen) Technology Co., Ltd
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Halolife (Xiamen) Technology Co., Ltd
	Detail of stability batches of drug product	Attached in 3.2.P.8
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in 3.2.P.8
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in 3.2.P.2.2.1
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 Months (zone IV A)

	The status in reference regulatory authorities	JOURNAVX (Vertex Pharmaceuticals Incorporated)
	GMP status of the firm	valid till 2027
	Evidence of approval of manufacturing facility	Tablet Section
	Evaluation Remarks	
	Export Facilitation	
	Decision	
	Approved	
132	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	(AVM-DQB-789V, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-20,
	The proposed proprietary name / brand name	**Cefzima**
	Label Claim	Each vial contains: Ceftazidime pentahydrate eq. to Ceftazidime.....2gm Avibactam sodium eq to Avibactam.....0.5gm (As per Innovators specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 YearStore in the original package in order to protect from light.
	For generic drugs (me-too Status)	seraph pharmaceuticals
	Pharmacotherapeutic Group of (API)	Qilu Antibiotics Pharmaceutical CO., Ltd. No.849 Dongjia town Licheng District China 250105 Jinan,Shangdong Province.
	Name, address of Manufacturing site:	Seraph pharmaceuticals-plot no 210, Industrial triangle kahuta road Islamabad pakistan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	330, Cefavidime
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
133	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hisun Pharmaceutical Industries** 37-A, R-2 Industrial Estate Gadoon, Amazi **(000624)**
	Application Form Dy. No / Tracking ID & date of submission	(BWQ-PQ4-X1JJ, 2026-08-20)

	Detail of Fee Submitted	97200, 2026-06-09,
	The proposed proprietary name / brand name	**Optiwin-D Eye Drops**
	Label Claim	Each ml of Suspension Contains: Dexamethasone.....1mg Tobramycin.....3mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	TOBRADEX SUSPENSION by Novartis Pharma, Pakistan 091915
	Pharmacotherapeutic Group of (API)	Antibiotic/ Corticosteriods
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE Super Highway, Phase-II, Karachi-
	The status in reference regulatory authorities	TOBRADEX SUSPENSION by Novartis Pharma USFDA Approved
	Detail of previous approval	Tobton-D Eye Drops approved in 333rd meeting of DRAP
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
134	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	(D28-QGT-X85Q, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-19,
	The proposed proprietary name / brand name	**Amlodotn 5/80 mg Tablets**
	Label Claim	Each Film Coated Tablet Contains; Amlodipine besylate (equivalent to Amlodipine) .....5mg Valsartan 80mg
	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)	Extor Tablet 5mg+80mg by The Searle Company Limited.
	Pharmacotherapeutic Group of (API)	Antihypertensive
	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	MHRA Approved.

	Detail of previous approval	Minutes of 336th meeting of Registration Board (4th to 6th June, 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved 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	(D2G-P9Z-6JWW, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Sofomycin 3g Sachet**
	Label Claim	Each Sachet Contains Fosmomycin 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 Year30C
	For generic drugs (me-too Status)	OBS Fosfo 3g Sachet
	Pharmacotherapeutic Group of (API)	phosphonic acid antibiotic
	Name, address of Manufacturing site:	Solaris Life Sciences Pvt. Ltd.-Plot # 08 Street No. S1 RCCI Industrial Estate Rawat Rawalpindi Pakistan.-
	The status in reference regulatory authorities	Swissmedic
	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 Approved	
136	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	(D75-ESS-DU68, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Eric 100mg ODT Tablets**
	Label Claim	Each Orodispersible Tablet contains: Sildenafil as Citrate .....100mg (Innovator Spec's.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 1, 4 x 1, 8 x 1, 12 x 1 or 24 x 1 orodispersible tablet in a box., As per SRO-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30□C. Store in the original package in order to protect from moisture.
	For generic drugs (me-too Status)	New Molecule
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic GMP-specificphosphodiesterase (Type V) with vasodilator action; 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	MHRA Approved
	Detail of previous approval	RIPPLE ODT 100mg Tablets, DRB 357
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
137	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Jinnah Pharmaceuticals Pvt Ltd** 13 Km Lahore Road Multan **(000578)**
	Application Form Dy. No / Tracking ID & date of submission	(DEL-7LE-SS83, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Jazolid infusion 600 mg /300 ml**
	Label Claim	Each Vial contains: Commitment Linezolid 600mg/300ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1`s-As per SRO
	Shelf Life (Unit)	2 YearRoom Temprature
	For generic drugs (me-too Status)	Nezkil 600mg Infusion Reg No 048804 S.J.&G Fazul Ellahie Pvt Ltd

	Pharmacotherapeutic Group of (API)	Oxazolidinone antibiotic
	Name, address of Manufacturing site:	Jaskan Pharmaceuticals (Pvt.) Ltd. -50-Sundar Industrial Estate, Lahore, Pakistan.-
	The status in reference regulatory authorities	Zyvox 2 mg/ml solution for infusion Pfizer Limited/ UK
	Detail of previous approval	DRB M-336 Reg 131379
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
138	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Epoch pharma** Plot No 83-85 Sector 15 korangi Industrial Area **(000425)**
	Application Form Dy. No / Tracking ID & date of submission	(DMS-3DT-V9LW, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-03-26,
	The proposed proprietary name / brand name	**Kilbac Injection 1gm**
	Label Claim	Each vial contains: Cefoperazone Sodium eq. to Cefoperazone.....500mg + Sulbactam Sodium eq. to Sulbactam.....500mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Sulzone 1.0Gm Injection by Biocare Pharmaceutica , 807-Shadman-I, Lahore,
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE Super Highway, Phase-II, Karachi-
	The status in reference regulatory authorities	Cefobid Injection Pfizer Pvt. Ltd. approved by FDA
	Detail of previous approval	Cefo-Qph 1gm Injection approved in 352 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 Approved	
139	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(DVH-QG1-3PH6, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-09,
	The proposed proprietary name / brand name	**Motepride 2mg Tablet**
	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	30's, and as per SRO-As per SRO
	Shelf Life (Unit)	2 YearAs required
	For generic drugs (me-too Status)	Prucic 2mg Tablet by Searle Company Ltd.
	Pharmacotherapeutic Group of (API)	As previously submitted
	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	Prucalopride 2mg film-coated tablets by axunio Pharma GmbH, MHRA approved
	Detail of previous approval	Prucalopride Succinate 2mg Tablet, DRB-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 Approved	
140	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**wise pharmaceuticals** Plot No 3-A, Street No S-1 RCCI Industrial Estate Rawat. Rawalpindi **(000625)**
	Application Form Dy. No / Tracking ID & date of submission	(DZV-B74-RN8B, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-02-26,
	The proposed proprietary name / brand name	**ULTECH 40mg INJECTION**
	Label Claim	Each vial contains: Esomeprazole sodium equ. to Esomeprazole 40mg
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Koncept 40mg Injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Name, address of Manufacturing site:	M/s Swera Pharmaceuticals-Plot# 27, Street# S-4, Rawat, Islamabad-
	The status in reference regulatory authorities	Nexium I.V 40mg Injection
	Detail of previous approval	M-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 Approved	
141	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)**
	Application Form Dy. No / Tracking ID & date of submission	(E7P-T28-6YUV, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-08,
	The proposed proprietary name / brand name	**REFMO 0.3% CREAM**
	Label Claim	Each Gm Cream Contains: Roflumilast..... .....3mg (0.3%) (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 25c
	For generic drugs (me-too Status)	Rofmil Cream 0.3% By Wezen Pharmaceuticals Reg No. 129506
	Pharmacotherapeutic Group of (API)	Phosphodiesterase Inhibitors
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat. -
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	REFMO 0.3% Cream, DRB 347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved Approved	
142	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**MRCK Pharmaceutical Laboratories (Pvt) Ltd** Plot No. 537-D&E, Sundar Estate, Raiwind Road Lahore **(000753)**
	Application Form Dy. No / Tracking ID & date of submission	(EB8-6PN-E9SV, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-10,
	The proposed proprietary name / brand name	**Omimoxa 400mg Tablet**
	Label Claim	Each film coated Tablet contains: Moxifloxacin as Hydrochloride .....400mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 5s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Sami Pharmaceutical Mofest 400mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotic
	Name, address of Manufacturing site:	Himark Laboratories(Pvt) Ltd-Plot No.37 Sundar industrial estate Lahore-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	322nd-RB -521-525 Moxifloxacin tab 400
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
143	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(ENM-H54-3V4E, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-25,
	The proposed proprietary name / brand name	**Levcron 1gm Injection**
	Label Claim	Each Ampoule (5mL) Contains: Levocarnitine (USP) .....1000mg (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 Yearbelow 25c
	For generic drugs (me-too Status)	KEFEI INJECTION by R.G. PHARMACEUTICA (PVT) LTD KARACHI
	Pharmacotherapeutic Group of (API)	Metabolic & Endocrine
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Block - B, Phase V, Industrial Estate Hattar.-
	The status in reference regulatory authorities	UK MHRA
	Detail of previous approval	L-Carta 1gm injection, DRB 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
144	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	(GMP-QZV-H7ZB, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-19,
	The proposed proprietary name / brand name	**AZ-TN 200mg / 5ml Suspension**
	Label Claim	Each reconstituted 5ml contains: Azithromycin (As Dihydrate) .....200mg (USP Specs.).
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	azitma suspension by Sami Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antibiotics
	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	MHRA Approved.
	Detail of previous approval	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	

	Approved	
145	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	(H7A-3X8-21XN, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-01-28,
	The proposed proprietary name / brand name	**LUFENZA**
	Label Claim	Each gram contains: Luliconazole.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore at Below 30C
	For generic drugs (me-too Status)	Zalea(Genix Pharma (Private) Limited)
	Pharmacotherapeutic Group of (API)	M/s. Optimus Drugs Private Limited
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd-44-45-B,Korangi creek Road Karachi-
	The status in reference regulatory authorities	LUZU (Valeant Pharmaceuticals)
	Detail of previous approval	Zalea, 340th 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 Approved	
146	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	(HS8-XXD-6PZ8, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Cadotril 10mg Sachet**
	Label Claim	Each Sachet Contains: Racecadotril 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)	Acetril 10 mg Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Antidiarrheal
	Name, address of Manufacturing site:	Solaris Life Sciences Pvt. Ltd-Plot # 08 Street No. S1 RCCI Industrial Estate Rawat Rawalpindi

		Pakistan.-
	The status in reference regulatory authorities	Registered in France
	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 Approved	
147	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	(HUA-LE4-4PZX, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-11,
	The proposed proprietary name / brand name	**EMPANIC 10mg TABLET**
	Label Claim	Each Film Coated tablet contains: Empagliflozin 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Celsius
	For generic drugs (me-too Status)	Empozin 10mg Tablet by M/s Macter International
	Pharmacotherapeutic Group of (API)	Data Already approved in 352 MoM
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Jardiance Tablet 10mg , FDA Approved
	Detail of previous approval	Empacal Tablet 10mg in 352 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 Approved	
148	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	(J17-XGJ-XXLU, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-03,
	The proposed proprietary name / brand name	**Satin 20mg Tablet**
	Label Claim	Each Uncoated Tablet contains: Bilastine.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10s-As per SRO,2X10s-As per SRO,3X10s-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:	Wezen Pharmaceuticals-Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
149	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**MRCK Pharmaceutical Laboratories (Pvt) Ltd** Plot No. 537-D&E, Sundar Estate, Raiwind Road Lahore **(000753)**
	Application Form Dy. No / Tracking ID & date of submission	(JEY-RVE-A862, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-19,
	The proposed proprietary name / brand name	**AumFeri 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 as Ferric Carboxymaltose
	Name, address of Manufacturing site:	Rukha Pharmaceutical Laboratories Pvt. Ltd.-Plot No. 537-D & E, Sunder Industrial Estate, Raiwind Road, Lahore.-

	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 Approved	
150	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**gulfpharmaceuticals** Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. **(000750)**
	Application Form Dy. No / Tracking ID & date of submission	(JUR-DXU-VD33, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-09,
	The proposed proprietary name / brand name	**Relmus**
	Label Claim	Each capsule contains Thiocolchicoside 4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's , 30's-As per SRO
	Shelf Life (Unit)	2 YearStore in room temprature
	For generic drugs (me-too Status)	Thioget 4mg of Getz Pharma
	Pharmacotherapeutic Group of (API)	Muscle relaxant
	Name, address of Manufacturing site:	M/s Carer Pharmaceuticals industries-Plot No. 27 main road, RCCI Industrial Estate Rawat Islamabad-
	The status in reference regulatory authorities	ANSM
	Detail of previous approval	Muscolax 4mg capsule, 357th meeting of RB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
151	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	(L6T-H13-WJ4Q, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-11,
	The proposed proprietary name / brand name	**Thiofaas 4mg/2ml Injection**
	Label Claim	Each 2ml ampoule contains: Thiocolchicoside 4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Brand Name: Muscoril Injection 4mg/2ml Registration holder: Searle Pharmaceuticals
	Pharmacotherapeutic Group of (API)	MYORELEXANT
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	ANSM France
	Detail of previous approval	Tiofrel, 335th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
152	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	(LAU-34N-B48Y, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-15,
	The proposed proprietary name / brand name	**Tovisolu Injection 100mg**
	Label Claim	Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone..... 100 mg 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)	Cortizone 100mg Injection By Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Biogen Life Sciences -8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	307th minutes of meeting

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
153	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	(LHT-JW1-1W2D, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-04,
	The proposed proprietary name / brand name	**Tampress-D Cap 0.4/0.5 mg**
	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	2X10'S-As per SRO,3X10'S-As per SRO,6x10's-As per SRO,9x10's-As per SRO
	Shelf Life (Unit)	2 YearRoom Condition
	For generic drugs (me-too Status)	Maxflox-D Cap by M/S CCL Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Tamsulosin: Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan & Dutasteride M/s Softgel Health Care (Pvt) Ltd Survey No: 20/1, Vendalur Kelambakkam road, Pudupakkam Village, Kancheepuram District
	Name, address of Manufacturing site:	BIOGEN LIFE SCIENCES-8Km,Chakbeli Road Rawat, Rawalpindi-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Minutes of 335th meeting of Registration Board, (25 Apr 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	

	Approved	
154	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	**Jenner Pharmceuticals Pvt. Ltd** Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura **(000823)**
	Application Form Dy. No / Tracking ID & date of submission	(5GR-TQ5-RHG2, 2024-10-31)
	Detail of Fee Submitted	37000.0, 2024-10-16,
	The proposed proprietary name / brand name	**Jenlig Tablets 15mg**
	Label Claim	Each Film Coated Tablet Contains: Mirogabalin As Besylate 15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s, 20s, 30s & 7s, -De-Controlled
	Shelf Life (Unit)	24 Year(s)Store below 30oC
	For generic drugs (me-too Status)	Mirogab 15mg Tablet by Nabiqasim
	Pharmacotherapeutic Group of (API)	Mirogabalin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of three batches at long term and accelerated studies
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at long term and accelerated studies
	The status in reference regulatory authorities	Tarlige Tablets by M/s Daiichi Sankyo, Japan, (Pharmaceuticals and Medical Devices Agency (PMDA) of Japan)
	GMP status of the firm	DML renewal w.e.f, 30-07-2025
	Evidence of approval of manufacturing facility	DML renewal w.e.f, 30-07-2025
	Evaluation Remarks	
	Decision	
	Approved	
155	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(LNJ-5R4-2PMP, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-19,
	The proposed proprietary name / brand name	**MIROTAR TABLET 2.5MG**
	Label Claim	Each Film Coated Tablet Contains: Mirogabalin Besylate eq.to Mirogabalin 2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	3 Yearas required

	For generic drugs (me-too Status)	Mirogab 2.5mg Tablet by Wimits Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Gabapentinoid medication primarily used for the treatment of neuropathic pain
	Name, address of Manufacturing site:	WIMITS PHARMACEUTICALS (PVT). LTD - Sunder Industrial Estate Lahore, Pakistan-
	The status in reference regulatory authorities	Tarlige Tablets by Daiichi Sankyo PMDA Approved
	Detail of previous approval	Mirogab 2.5mg Tablet Approved in DRB 344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
156	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	(MJR-NV4-68HN, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-11,
	The proposed proprietary name / brand name	**EMPANIC-LT 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	2x7's; 1x14's; 2x14's; 4x7's; 3x10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Celsius
	For generic drugs (me-too Status)	Diampa-LT 10mg/5mg Tablet by M/s Getz Pharma
	Pharmacotherapeutic Group of (API)	Data Already approved in 353 MoM
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Glyxambi 10 mg/5 mg film-coated tablets , FDA Approved
	Detail of previous approval	Empacal-LT Tablet 10mg/5mg in 353 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 Approved	
157	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	**Jenner Pharmceuticals Pvt. Ltd** Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura **(000823)**
	Application Form Dy. No / Tracking ID & date of submission	(ZVT-EZ8-3133, 2024-10-30)
	Detail of Fee Submitted	37000.0, 2024-10-16,
	The proposed proprietary name / brand name	**Jenlig Tablets 10mg**
	Label Claim	Each Film Coated Tablet Contains: Mirogabalin As Besylate 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s, 20s, 30s & 7s, -De-Controlled
	Shelf Life (Unit)	24 Year(s)Store below 30oC
	For generic drugs (me-too Status)	Mirogab 10mg Tablet by Nabiqasim
	Pharmacotherapeutic Group of (API)	DML renewal w.e.f, 30-07-2025
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of three batches at long term and accelerated studies
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at long term and accelerated studies
	The status in reference regulatory authorities	Tarlige Tablets by M/s Daiichi Sankyo, Japan, (Pharmaceuticals and Medical Devices Agency (PMDA) of Japan)
	GMP status of the firm	Dated 05-07-2022
	Evidence of approval of manufacturing facility	DML No 000823
	Evaluation Remarks	
	Decision	
	Approved	
158	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**PERFECT PHARMA (PVT) LTD** 5Km, Manga Road, Raiwind, Lahore **(000469)**
	Application Form Dy. No / Tracking ID & date of submission	(NN7-LS4-59D6, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-11,
	The proposed proprietary name / brand name	**MEROPARIN 500mg Injection**
	Label Claim	Each vial contains: Meropenem trihydrate USP eq. to Meropenem.....500mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year25
	For generic drugs (me-too Status)	MOPEN Injection
	Pharmacotherapeutic Group of (API)	Carbapenem
	Name, address of Manufacturing site:	DEW-MAX PHARMACEUTICAL PVT LTD-Plot # 6, St SS4, Main industrial area, Rawat, Islamabad, Pakistan-
	The status in reference regulatory authorities	(MERREM 500mg Injection), M/s. AstraZeneca USA
	Detail of previous approval	Dewnem 500mg Injection,Meeting No 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 Approved	
159	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**
	Application Form Dy. No / Tracking ID & date of submission	(PB6-QDX-WHMB, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-04,
	The proposed proprietary name / brand name	**LOTENMYCIN EYE DROPS 5mg +3mg/mL**
	Label Claim	Each ml of ophthalmic suspension contains: Loteprednol Etabonate.....5mg Tobramycin 3mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 YearStore between 15°C to 25°C. Protect from sunlight& moisture
	For generic drugs (me-too Status)	Lotetob Opthalmic Suspension
	Pharmacotherapeutic Group of (API)	Corticosteroid and Anti-infective Combinations
	Name, address of Manufacturing site:	M/S Winthrox Pharmaceuticals (Pvt) Ltd-K-291-A, S.I.T.E, Super Highway, Karachi-
	The status in reference regulatory authorities	Zylet Eye Drops
	Detail of previous approval	Lotinon Eye drops, Minutes of 333 drug Registration board held on 19th - 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 Approved	
160	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Epoch pharma** Plot No 83-85 Sector 15 korangi Industrial Area **(000425)**
	Application Form Dy. No / Tracking ID & date of submission	(PEM-7SR-6VLW, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-03-26,
	The proposed proprietary name / brand name	**Osit Tablet 8mg**
	Label Claim	Each film-coated tablet contains: Ondansetron Hydrochloride (as Dihydrate) equivalent to Ondansetron... 8mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Onsetron Tablets 8mg 062816 by Dyson Research Laboratories (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Antiemetic
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE Super Highway, Phase-II, Karachi-
	The status in reference regulatory authorities	Ondansetron Tablet Approved By Health Canada
	Detail of previous approval	Ondesty 8mg Tablet Approved in 336th Meeting DRB dated 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 Approved	
161	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	(PR3-T7P-Y4ZX, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-04,
	The proposed proprietary name / brand name	**AUROXONE 250MG IV**

	Label Claim	Each vial contains: Ceftriaxone (as sodium) .....250mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearRoom Condition
	For generic drugs (me-too Status)	Inocef (Barrett Hodgson Pakistan Pvt Ltd. 056509)
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Name, address of Manufacturing site:	BIOGEN LIFE SCIENCES-8Km,Chakbeli Road Rawat, Rawalpindi-
	The status in reference regulatory authorities	DRAP
	Detail of previous approval	Ceftigen 250 mg IV (108044), 297 MINUTES OF MEETTING
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
162	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Cell Health Sciences,** Plot No 217, Industrial Triangle, Kahuta Road, Islamabad **(000711)**
	Application Form Dy. No / Tracking ID & date of submission	(PRX-4TX-H69Y, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-19,
	The proposed proprietary name / brand name	**Perocell 1gm/100ml Infusion**
	Label Claim	Each 100ml vial contains: Paracetamol.....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Provas 1g/100ml Infusion of M/s SAMI Pharma
	Pharmacotherapeutic Group of (API)	Other Analgesics And Antipyretics.
	Name, address of Manufacturing site:	Skywin Pharmaceutical Pvt. Ltd-Plot # 01, AL Badar Idustrial Estate Phase II, Sheikhupura Road, Sheikhupura Sheikhupura-
	The status in reference regulatory authorities	Paracetamol ALTAN 10 mg/mL solution for infusion of M/s Martindale Pharma, an Ethypharm Group Company Address: Jupiter House, Mercury Park, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, UK (MHRA Approved)
	Detail of previous approval	Skydol Infusion approved in 344th Meeting of DRB

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
163	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(PYU-X9P-5ZR7, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-09,
	The proposed proprietary name / brand name	**Motepride 1mg Tablet**
	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	30's, and as per SRO-As per SRO
	Shelf Life (Unit)	2 YearAs required
	For generic drugs (me-too Status)	Prucic 1mg Tablet by Searle Company Ltd.
	Pharmacotherapeutic Group of (API)	As previously submitted
	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	Prucalopride 1 mg film-coated tablets by axunio Pharma GmbH, MHRA Approved
	Detail of previous approval	Prucalopride Succinate 1mg Tablet, 343rd 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 Approved	
164	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	(PX8-63L-X4JY, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-11,
	The proposed proprietary name / brand name	**AURCOSIDE 4MG CAP**
	Label Claim	Each Capsule Contains: Thiocolchicoside...4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10-As per SRO,2X10'S-As per SRO,3X10'S-As per SRO,4X10'S-As per SRO,6X10'S-As per SRO
	Shelf Life (Unit)	2 YearRoom Condition
	For generic drugs (me-too Status)	Thioget 4mg Cap. M/S Getz Pharma (Reg. No. 086076)
	Pharmacotherapeutic Group of (API)	Muscle Relaxant
	Name, address of Manufacturing site:	Career Pharmaceuticals Industries-Plot No 27, Main Raod, Rawat Industrial Estate, Rawat.-
	The status in reference regulatory authorities	ANSM (France) approved.
	Detail of previous approval	Muscolax 4mg Cap (Minutes of 357th meeting of Registration Board 21 Apr 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	
	Approved Approved	
165	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**gulfpharmaceuticals** Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. **(000750)**
	Application Form Dy. No / Tracking ID & date of submission	(Q2B-2QP-GDQA, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-09,
	The proposed proprietary name / brand name	**Samper DS**
	Label Claim	Each film coated tablet contains: Tramadol HCl.....75mg Paracetamol..... 650mg
	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)	Tonoflex-p tablet of Sami
	Pharmacotherapeutic Group of (API)	Opioids in combination with non-opioid analgesics
	Name, address of Manufacturing site:	Biogen Pharmaceuticals-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Ultracet® Tablet USFDA

	Detail of previous approval	Paradol D tablet in 335th meeting of RB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
166	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Obsons Pharmaceuticals** 209-S Quaid-e-Azam industrial estate, **(000416)**
	Application Form Dy. No / Tracking ID & date of submission	(Q5P-H6E-PQ2B, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-04,
	The proposed proprietary name / brand name	**Tazopime 2.5 g Injection**
	Label Claim	Each vial contains: Piperacillin (as Sodium) 2.0g Tazobactam (as Sodium) 0.25g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 1's-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature
	For generic drugs (me-too Status)	Inzalin TZ 2.25g Injection
	Pharmacotherapeutic Group of (API)	β-Lactamase inhibitor
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Badar Industrial Estate, Phase II, Sheikhupura Road, Lahore, Pakistan. -
	The status in reference regulatory authorities	USFDA Approve5
	Detail of previous approval	Inzalin TZ 2.25g Injection, 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 Approved	
167	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	(Q7J-BJ2-TRRX, 2026-08-20)
	Detail of Fee Submitted	93000, 2025-06-25,
	The proposed proprietary name / brand name	**TERBIORA**
	Label Claim	Each gram contains: Terbinafine Hydrochloride.....1%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5g,10g,15g,30g-As per SRO
	Shelf Life (Unit)	2 YearStore at Below 30C
	For generic drugs (me-too Status)	Tinasil (Akhai Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	M/S Saptagir Laboratories Pvt Ltd
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd-44-45-B,Korangi creek Road Karachi-
	The status in reference regulatory authorities	Lamisil (Novartis Pharmaceuticals Corporation)
	Detail of previous approval	AFERT Cream, 339th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
168	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hisun Pharmaceutical Industries** 37-A, R-2 Industrial Estate Gadoon, Amazi **(000624)**
	Application Form Dy. No / Tracking ID & date of submission	(QE1-4HR-Z838, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-09,
	The proposed proprietary name / brand name	**Optiwin Eye Drop**
	Label Claim	Each ml of solution contains: Tobramycin .....3mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	TOBREX OPHTHALMIC SOLUTION BY NOVARTIS PHARMA REG. NO. 008249
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE Super Highway, Phase-II, Karachi-
	The status in reference regulatory authorities	Tobrex Ophthalmic Solution by Novartis Pharma FDA Approved
	Detail of previous approval	Minutes of 333rd Meeting of Registration Board held on 19th-20th December 2023 with brand name of Tycin Ophthalmic 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 Approved	
169	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**MRCK Pharmaceutical Laboratories (Pvt) Ltd** Plot No. 537-D&E, Sundar Estate, Raiwind Road Lahore **(000753)**
	Application Form Dy. No / Tracking ID & date of submission	(QJ3-2XG-GX4H, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-10,
	The proposed proprietary name / brand name	**Omifloxa 500mg Tablet**
	Label Claim	Each film coated Tablet contains: Ciprofloxacin Hydrochloride Eq. Ciprofloxacin..... 500mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 10s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	M/s Indus Pharma Ciplet 500 mg F/C Tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotic
	Name, address of Manufacturing site:	M/s Himark Laboratories(Pvt) Ltd-Plot No.37 A Sundar industrial estate-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	307th-RB ciprofloxacin HCl Tab 250 and 500 462-478
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
170	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(QT9-J9M-ZAXN, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-09,
	The proposed proprietary name / brand name	**Tedizol Injection 200mg**
	Label Claim	Each vial contains: Tedizolid phosphate.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 C
	For generic drugs (me-too Status)	Tediz Injection 200mg
	Pharmacotherapeutic Group of (API)	Oxazolidinone-class antibacterial
	Name, address of Manufacturing site:	SAMI Pharmaceuticals Pvt. Ltd.- F-95 Hub River Road S.I.T.E Karachi-
	The status in reference regulatory authorities	Food and Drug Administration
	Detail of previous approval	345 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 Approved	
171	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(QWW-UBP-AXQA, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-17,
	The proposed proprietary name / brand name	**C-Dosin 8mg Capsules**
	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-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C.
	For generic drugs (me-too Status)	Registered in Pakistan (Silorap 8mg capsules by Gets Pharma)
	Pharmacotherapeutic Group of (API)	M/S:Anhui Haikang Pharmaceutical co,ltd. Address:No.21 Huanchang west road Anqing city,Anhui province 246000(china)
	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	USFDA Approved
	Detail of previous approval	Siloton 8mg Capsules, 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 Approved	
172	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	(QY8-761-VEDD, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Replay 20mg Tablet**
	Label Claim	Each filmcoated tablet contains: Tadalafil 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Talda 20mg Tablet Medizan
	Pharmacotherapeutic Group of (API)	Urologicals
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	358TH meeting approved
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
173	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	(RE1-2XL-A716, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-25,

	The proposed proprietary name / brand name	**Nepa Tan Forte Ophthalmic Suspension**
	Label Claim	Each ml contains: Nepafenac ..... 3mg (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 YearStore below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Nepatek TS 0.3% Ophthalmic Suspension 3ml by Innvotek Pharmaceuticals
	Pharmacotherapeutic Group of (API)	NSAIDs
	Name, address of Manufacturing site:	OPTIMUS LABORATORIES (Pvt). Ltd. -Plot no 62,Bhalwal Industrial Estate, Bhalwal, District Sargodha.-
	The status in reference regulatory authorities	EMC Approved.
	Detail of previous approval	354th 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 Approved	
174	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	(RMQ-T3H-GDRE, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-12,
	The proposed proprietary name / brand name	**PATEYE 0.2% Ophthalmic Solution**
	Label Claim	Pateye 0.2% Ophthalmic Suspension: Olopatadine HCl eq.to Olopatadine ..... 0.2% w/v (USP 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)	Olopharm Ophthalmic Solution by Epharm Laboratories
	Pharmacotherapeutic Group of (API)	Selective H1-receptor antagonists
	Name, address of Manufacturing site:	OPTIMUS LABORATORIES (Pvt). Ltd-Plot no 62,Bhalwal Industrial Estate, Bhalwal, District Sargodha.-
	The status in reference regulatory authorities	FDA approved
	Detail of previous approval	354 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 Approved	
175	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	(RNW-R55-98AZ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-04,
	The proposed proprietary name / brand name	**Auroxone 500mg Injection I.V**
	Label Claim	Each Vial Contains: Ceftriaxone (as sodium).....500mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearRoom Condition
	For generic drugs (me-too Status)	Rocephin Inj by Roche
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Name, address of Manufacturing site:	BIOGEN LIFE SCIENCES-8Km,Chakbeli Road Rawat, Rawalpindi-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	CARE 500MG IV INJ, 297 Minutes Of Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
176	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**MRCK Pharmaceutical Laboratories (Pvt) Ltd** Plot No. 537-D&E, Sundar Estate, Raiwind Road Lahore **(000753)**
	Application Form Dy. No / Tracking ID & date of submission	(RNX-VEN-WVTU, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-10,
	The proposed proprietary name / brand name	**Omifloxa 250mg Tablet**

	Label Claim	Each film coated Tablet contains: Ciprofloxacin Hydrochloride Eq. Ciprofloxacin.....250mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	M/s Indus Pharma Ciplet 500 mg F/C Tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotic
	Name, address of Manufacturing site:	M/s Himark Laboratories(Pvt) Ltd-Plot 37-A Sundar industrial estate-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	307th-RB ciprofloxacin HCl Tab 250
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
177	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	(RP2-7AJ-JAW5, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**MONTES 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 Year30C
	For generic drugs (me-too Status)	SOLKAST 4 mg Granules
	Pharmacotherapeutic Group of (API)	Leukotriene Receptor Antagonists LTRAs
	Name, address of Manufacturing site:	Solaris Life Sciences Pvt. Ltd-Plot # 08 Street No. S1 RCCI Industrial Estate Rawat Rawalpindi Pakistan.-
	The status in reference regulatory authorities	USFDA
	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 Approved	
178	Case Category	Contract Manufacturing (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	(RYM-SH4-PBDS, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**KET-NAG 30mg Injection**
	Label Claim	Each ml Contains: Ketorolac Tromethamine= 30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5’s, 10’s, 30’s-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C
	For generic drugs (me-too Status)	Toradol by M/S Martin Dow
	Pharmacotherapeutic Group of (API)	NSAIDS
	Name, address of Manufacturing site:	M/s. May & Baker (Pvt) Ltd-45-Km, Dina Nath, Multan Road, Lahore-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Porposed Name: Ketorol 30mg/ml injection in Meeting NO.323, Current/Approved Brand name: Ket-May 30mg/ml 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 Approved	
179	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	(SG3-GJP-7MMQ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-01,
	The proposed proprietary name / brand name	**Mon-Tan 0.5% Ophthalmic Solution**
	Label Claim	Each ml contains: Moxifloxacin HCl equivalent to Moxifloxacin.....5mg (USP Specs).

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Ocumox Eye Drops by Macquin's International
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	OPTIMUS LABORATORIES (Pvt). Ltd.-Plot no 62,Bhalwal Industrial Estate, Bhalwal, District Sargodha.-
	The status in reference regulatory authorities	FDA approved
	Detail of previous approval	354 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 Approved	
180	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Bloom Pharmaceuticals (Pvt) Ltd.** Plot No. 30, Phase I & II, Industrial Estate, Hattar **(000374)**
	Application Form Dy. No / Tracking ID & date of submission	(SGD-LT4-MYGZ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-15,
	The proposed proprietary name / brand name	**FRIC-C Injection**
	Label Claim	Each 10ml Vial Contains: Iron as Ferric Carboxymaltose.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10mlX 10S (Vial)-As per SRO,10mlX1S (Vial)-As per SRO,10mlX5S (Vial)-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:	Wnsfeild Pharmaceuticals -Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	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 Approved	
181	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(SJZ-PAL-L2AH, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-05,
	The proposed proprietary name / brand name	**MIROTAR TABLET 5MG**
	Label Claim	Each Film Coated Tablet Contains: Mirogabalin Besylate eq.to Mirogabalin 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	3 Yearas required
	For generic drugs (me-too Status)	Mirogab 5mg Tablet by Wimits
	Pharmacotherapeutic Group of (API)	Gabapentinoid medication primarily used for the treatment of neuropathic pain
	Name, address of Manufacturing site:	WIMITS PHARMACEUTICALS (PVT). LTD - Sunder Industrial Estate Lahore, Pakistan-
	The status in reference regulatory authorities	Tarlige Tablets by Daiichi Sankyo PMDA Approved
	Detail of previous approval	Mirogab 5mg Tablet Approved in DRB 344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
182	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Panacea Pharmaceuticals** plot No 04,Street S-6 National industrial Zone RCCI rawat islamabad **(000600)**
	Application Form Dy. No / Tracking ID & date of submission	(SUD-31A-XAXE, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-25,
	The proposed proprietary name / brand name	**Vonit 10mg Tablets**
	Label Claim	Each Film Coated Tablet Conatins: Vonoprazan Fumarate Eq.to Vonoprazan ..... 10mg. (Innovators' Specifications).
	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 10mg Tablet (Getz Pharma)
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Name, address of Manufacturing site:	M/s Pine Pharmaceuticals-Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.-
	The status in reference regulatory authorities	PMDA Japan Approved
	Detail of previous approval	Vonoprazon 10mg Tablet, 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 Approved	
183	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	(B3B-37L-833U, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**Dorzoptic 2%/0.5% Eye Drops**
	Label Claim	Each ml contains: Dorzolamide HCl e. to Dorzolamide... 20mg Timlol maleate eq. to Timlol ....5mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 Year15C-25C
	For generic drugs (me-too Status)	Dorlol 5ml Eye Drops by Genix Pharma
	Pharmacotherapeutic Group of (API)	carbonic anhydrase inhibitors and beta-blockers.
	Name, address of Manufacturing site:	MEDEVO (PRIVATE) LTD.-Plot no. 94 Sunder industrial Estate Raiwind, Lahore-
	The status in reference regulatory authorities	COSOPT ophthalmic Solution by SANTEN PHARMA CO.,LTD. JAPAN
	Detail of previous approval	Medidor-T Eye Drops- M336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved Approved	
184	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	(YLP-P7N-NH3E, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-07,
	The proposed proprietary name / brand name	**Tazocillin 2.25g Injection**
	Label Claim	Each vial contains: Piperacillin sodium equivalent to piperacillin..... 2 g Tazobactam sodium equivalent to Tazobactam..... 0.25 g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's, As per SRO-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25°C
	For generic drugs (me-too Status)	Tazonem Injection 2g/250mg by Medera Pharmaceuticals
	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 No.13-A, Street No. N-5, RCCI, Industrial Estate, Rawat, Rawalpindi-PAKISTAN-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	Talzon Injection, DRB 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 Approved	
185	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	(J16-NQM-LAGS, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-07,
	The proposed proprietary name / brand name	**Tazocillin 4.5g Injection**

	Label Claim	Each vial contains: Piperacillin sodium equivalent to piperacillin..... 4g Tazobactam sodium equivalent to Tazobactam..... 0.5g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25°C.
	For generic drugs (me-too Status)	PIPRAL-T 4.5gm Injection (IV) by Nimrall Laboratories
	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 No.13-A, Street No. N-5, RCCI, Industrial Estate, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Talzon Injection 4.5g, DRB 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 Approved	
186	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	**Scotmann Pharmaceuticals** Plot #5D , Industrial Area, I-10/3 Islamabad **(000498)**
	Application Form Dy. No / Tracking ID & date of submission	(PZ4-L6G-4352, 2024-09-27)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Mirotab Tablet 10mg**
	Label Claim	Each film coated tablet contains: Mirogabalin (as besylate)..... 10mg (Innovator's Specifications)
	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)Below 30 °C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	N02BF03: Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Source of Drug Substance: Shandong Kehui Pharmaceutical Co., Ltd. Address: No.1, Block A, Tianheng Road, Changjia Town, Gaoqing County, Zibo City, Shandong Province, China.
	Detail of stability batches of drug product	Data of three batches at long term and accelerated conditions

	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tarlige Tablet 10mg, Batch No. YCA 2064
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Tarlige Tablet 10mg, Registered in Pharmaceuticals and Medical Devices Agency (PMDA)
	GMP status of the firm	DML Renewal ,w.e.f.. 22-06-2022
	Evidence of approval of manufacturing facility	DML Renewal ,w.e.f.. 22-06-2022
	Evaluation Remarks	
	Decision	
	Approved	
187	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	**Scotmann Pharmaceuticals** Plot #5D , Industrial Area, I-10/3 Islamabad **(000498)**
	Application Form Dy. No / Tracking ID & date of submission	(LVH-3M9-EVVZ, 2024-08-23)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Mirotab Tablet 5mg**
	Label Claim	Each film coated tablet contains: Mirogabalin (as besylate)..... 5mg (Innovator's Specifications)
	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)Below 30 °C
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	ATC code: N02BF03; analgesic; gabapentinoid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Source of Drug Substance: Shandong Kehui Pharmaceutical Co., Ltd. Address: No.1, Block A, Tianheng Road, Changjia Town, Gaoqing County, Zibo City, Shandong Province, China.
	Detail of stability batches of drug product	Data of three batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tarlige Tablet 5mg, Registered in Pharmaceuticals and Medical Devices Agency (PMDA) Batch YBA2175
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	At long-term and accelerated conditions
	The status in reference regulatory authorities	Tarlige Tablet 5mg, Registered in Pharmaceuticals and Medical Devices Agency (PMDA)
	GMP status of the firm	Renewal of DML Report dated 22-02-2024 with recommendation for grant of renewal of DML
	Evidence of approval of manufacturing facility	DML 000498 valid

	Evaluation Remarks	
	Decision	
	Approved	
188	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	**Scotmann Pharmaceuticals** Plot #5D , Industrial Area, I-10/3 Islamabad **(000498)**
	Application Form Dy. No / Tracking ID & date of submission	(9HX-8ZN-BYSZ, 2024-08-30)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Mirotab Tablet 2.5mg**
	Label Claim	Each film coated tablet contains: Mirogabalin (as besylate)..... 2.5mg (Innovator's Specifications)
	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)Below 30 °C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	N02BF03: Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	Data of three batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tarlige Tablet 2.5mg, Batch No. YAA2084
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Tarlige Tablet 2.5mg, Registered in Pharmaceuticals and Medical Devices Agency (PMDA)
	GMP status of the firm	DML Renewal ,w.e.f.. 22-06-2022
	Evidence of approval of manufacturing facility	DML Renewal ,w.e.f.. 22-06-2022
	Evaluation Remarks	
	Decision	
	Approved	
189	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	**Scotmann Pharmaceuticals** Plot #5D , Industrial Area, I-10/3 Islamabad **(000498)**
	Application Form Dy. No / Tracking ID & date of submission	(2ML-YTB-MV83, 2024-09-18)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Mirotab Tablet 15mg**
	Label Claim	Each film coated tablet contains: Mirogabalin (as besylate)..... 15mg (Innovator's Specifications)
	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)Below 30 °C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	N02BF03: Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Source of Drug Substance: Shandong Kehui Pharmaceutical Co., Ltd. Address: No.1, Block A, Tianheng Road, Changjia Town, Gaoqing County, Zibo City, Shandong Province, China.
	Detail of stability batches of drug product	Data of three batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tarlige Tablet 15mg, Batch No. YDA 2023
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Tarlige Tablet 15mg, Registered in Pharmaceuticals and Medical Devices Agency (PMDA)
	GMP status of the firm	DML Renewal ,w.e.f.. 22-06-2022
	Evidence of approval of manufacturing facility	DML Renewal ,w.e.f.. 22-06-2022
	Evaluation Remarks	
	Decision	
	Approved	
190	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Al Fazal Pharma Industries (Pvt) Ltd.** Plot no. 20,21, 22 - Defence Industrial Zone - Momen Pura, 16 KM Sheikhupura Road Lahore **(000803)**
	Application Form Dy. No / Tracking ID & date of submission	(N3P-RRR-A9DB, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-18,
	The proposed proprietary name / brand name	**Isotrim 40mg soft gel capsule**
	Label Claim	Each Capsule contains: Isotretinoin ... 40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	3X10-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 degree
	For generic drugs (me-too Status)	Oratane 40mg soft gel capsule
	Pharmacotherapeutic Group of (API)	Retinoids
	Name, address of Manufacturing site:	M/S crystolite Pharmaceutical-Plot No. 1& 2 S-2, National Industrial zone Rawat-
	The status in reference regulatory authorities	Attached
	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 Approved	
191	Case Category	Routine (Incharge Evaluation Cell)
	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	(3PD-Q1N-AVME, 2024-09-18)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-12, 2024-09-12
	The proposed proprietary name / brand name	**Met-Flo Tablet**
	Label Claim	Each Film coated tablet contains: Metformin HCl.....850mg &Empagliflozin.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 7's-As per SRO
	Shelf Life (Unit)	24 Month25 degree
	For generic drugs (me-too Status)	Diampa-M by Getz pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LIMITED,Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat INDIA.,Zhejiang Huahai Pharmaceutical Co., Ltd. (Chuannan Site),Chuannan, Duqiao, Linhai, Zhejiang, 317016, 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	Synjardy 5 mg/850 mg tablets by Boehringer Ingelheim International GmbH
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
192	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(QMD-2NE-SZD4, 2026-08-20)

	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**Prostreat-D Capsule**
	Label Claim	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) ..... 0.5mg Tamsulosin HCl (as 0.2% modified release pellets) 0.4mg
	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)	Maxflow-D Capsule CCL Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Tamsulosin alpha blockers Dutosteride 5-alpha-reductase inhibitors (5-ARIs)
	Name, address of Manufacturing site:	Global Pharmaceuticals Pvt Ltd- Plot No. 204-205, Industrial triangle Kahuta Road Islamabad-Pakistan.-
	The status in reference regulatory authorities	Dutrozen 0.5 mg / 0.4 mg hard capsules (Zentiva Pharma UK Limited)
	Detail of previous approval	Tamu-D capsule 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 Approved	
193	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. **(000964)**
	Application Form Dy. No / Tracking ID & date of submission	(135-B8R-APLG, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-09,
	The proposed proprietary name / brand name	**V-tron 8mg/4ml Injection**
	Label Claim	Each 4ml contains Ondansetron HCl Dihydrate eq.to Ondansetron 8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25-30°C
	For generic drugs (me-too Status)	Onset 8mg/4ml Injection
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Name, address of Manufacturing site:	Hi-Med Pharmaceuticals-plot No 208-C ,Sunder Industrial estate,Lahore-
	The status in reference regulatory authorities	Ondansetron solution for Injection (MHRA Approved)

	Detail of previous approval	Ondit 8mg/4ml Injection in 352nd minutes of meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
194	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(YH6-3RQ-MHGJ, 2024-09-20)
	Detail of Fee Submitted	30000.0, 2024-07-31,
	The proposed proprietary name / brand name	**Linasian - M 2.5/850mg**
	Label Claim	Each Film Coated Tablet contains: Linagliptin.....2.5mg Metformin HCl.....850mg
	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 °C
	For generic drugs (me-too Status)	Linet 2.5/850mg (Titlis Pharma Pvt Ltd)
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti drug Limited ,Anhui Haikang Pharmaceutical Co. Ltd.
	Detail of stability batches of drug product	Data of three batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Jentadueto 2.5/850mg Tablet (Boehringer Ingelheim Germany)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	Decision	
	Approved	
195	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	**Batala Pharmaceuticals** 23-b, small industrial estate # 2, near wapda town, khiali bypass gujranwala **(000477)**
	Application Form Dy. No / Tracking ID & date of submission	(4MW-88G-4PS2, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-14,
	The proposed proprietary name / brand name	**ONBET 8MG/4ML INJECTION**
	Label Claim	Each 4ml contains: Ondansetron HCl Dihydrate eq. to Ondansetron.....8mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4mlx5's-As per SRO
	Shelf Life (Unit)	2 YearKeep the ampoules in the outer carton in order to protect from light.
	For generic drugs (me-too Status)	ONSERON 8mg/4ML INJECTION (Indus Pharma)
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Name, address of Manufacturing site:	Hi-Med Pharmaceutical -208-C Sundar Industrial Estate Raiwind Road Lahore, Punjab, Pakistan-
	The status in reference regulatory authorities	ONDANSETRON SANDOZ 8MG/4ML (Sandoz Canada Inc. 110 Rue de Lauzon Boucherville, Québec, Canada J4B 1E6) Health Canada Approved
	Detail of previous approval	Ondit 8mg/4ml injection Minutes of 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 Approved	
196	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Batala Pharmaceuticals** 23-b, small industrial estate # 2, near wapda town, khiali bypass gujranwala **(000477)**
	Application Form Dy. No / Tracking ID & date of submission	(7XU-8TR-YJJ7, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-14,
	The proposed proprietary name / brand name	**BROP-D3 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	1 ml x 1's-As per SRO

	Shelf Life (Unit)	2 Year- Keep- To be sol Do not freeze. - Keep in cool and dry place, protect from light. - Store below 30°C. - Do not use if solution is cloudy or it contains un-dissolved particle(s).
	For generic drugs (me-too Status)	Indrop-D Injection Neutro Pharma
	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	ANSM France Approved VITAMIN D3 GOOD 200,000 IU/1 ml, IM injection solution in ampoule ANSM (France) Approved
	Detail of previous approval	D3 Vibe Injection 5mg/ml minutes of meeting 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 Approved	
197	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(WDA-Z68-9H7A, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-06-20,
	The proposed proprietary name / brand name	**EMPAC-M 5mg/1000mg**
	Label Claim	Each film coated tablet contains: Empagliflozin.....5mg Metformin HCl.....1000mg
	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 °C
	For generic drugs (me-too Status)	Diampa-M 5mg/1000mg Tablet(Getz Pharma)
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti Drugs Limited,Fuxin Long Rui Pharmaceutical Co. Ltd.
	Detail of stability batches of drug product	Data of three batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Synjardy 5mg/1000mg Tablet (Boehringer Ingelheim Germany)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	Decision	
	Approved	
198	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Batala Pharmaceuticals** 23-b, small industrial estate # 2, near wapda town, khiali bypass gujranwala **(000477)**
	Application Form Dy. No / Tracking ID & date of submission	(WWX-TZZ-NUY4, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-15,
	The proposed proprietary name / brand name	**BFC 500MG /10 ML INJECTION**
	Label Claim	Each 10ml Contains: Iron as Ferric Carboxymaltose.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 1's-As per SRO
	Shelf Life (Unit)	2 YearStore at below 25 degree celcius,Do not freeze.
	For generic drugs (me-too Status)	Ferojin 500mg/10ml Injection Manufacturer/Registration holder: 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	: FERINJECT (Vifor Pharma Pty Ltd) TGA Approved
	Detail of previous approval	FBM-500 Injection 500mg/10ml, Meeting No. 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 Approved	
199	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	**Jenner Pharmceuticals Pvt. Ltd** Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura **(000823)**

	Application Form Dy. No / Tracking ID & date of submission	(W6B-E19-DJYZ, 2024-10-30)
	Detail of Fee Submitted	37000.0, 2024-10-16,
	The proposed proprietary name / brand name	**Jenlig Tablets 5mg**
	Label Claim	Each Film Coated Tablet Contains: Mirogabalin As Besylate 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s, 20s, 30s & 7s, -De-Controlled
	Shelf Life (Unit)	24 Year(s)Store below 30oC
	For generic drugs (me-too Status)	Mirogab 5mg Tablet by Nabiqasim
	Pharmacotherapeutic Group of (API)	N02BF03; Gabapentinoid analgesic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches of 700 tablets each at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from McOlson Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Tarlige Tablets by M/s Daiichi Sankyo, Japan, (Pharmaceuticals and Medical Devices Agency (PMDA) of Japan)
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	Decision	
	Approved Approved. The applicant shall submit fee for revision of specification before issuance of Registration Letter.	
200	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	(L53-RWE-1J23, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-30,
	The proposed proprietary name / brand name	**PESED PLUS 650/75mg tablets**
	Label Claim	Each film coated tabletcontains; Tramadol HCl..... 75 mg Paracetamol..... 650 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's, 30's & 10x10's-As per SRO
	Shelf Life (Unit)	3 YearRoom Condition
	For generic drugs (me-too Status)	Product Name: Tonoflex-p fort Tablet Composition: Each coated tablet contains; Tramadol HCl……. 75 mg

		Paracetamol……. 650 mg Sami Pharmaceutical Pakistan (Pvt.) ltd
	Pharmacotherapeutic Group of (API)	Analgesic & antipyretic
	Name, address of Manufacturing site:	Biogen Life Science -8-km, Chakbeli Road, Rawat Rawalpindi-
	The status in reference regulatory authorities	SRA Registration Status: UK approved Brand Name: Ultracet® Tramadol/Paracetamol 75 mg / 650 mg Tablets Manufacturer: by M/s Aspire Pharma Ltd. UK
	Detail of previous approval	Minutes of 335th meeting of Registration Board, with brand name of PARADOL D 75/650mg 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 Approved	
201	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	**Valor Pharmaceuticals** Plot No 124/A, Industrial Triangle, Kahuta Road, Islamabad **(000496)**
	Application Form Dy. No / Tracking ID & date of submission	(SEU-TAJ-W3W3, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2023-09-28,
	The proposed proprietary name / brand name	**Glifmet 12.5/500mg**
	Label Claim	Each film-coated tablet contains: Empagliflozin..... 12.5mg Metformin HCl.....500 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's-As per SRO
	Shelf Life (Unit)	2 YearControlled room temperature
	For generic drugs (me-too Status)	Diampa-M 12.5/500 mg
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Empagliflozin,Metformin HCl
	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	Australian GOVT

	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved. The applicant shall submit fee for revision of specification and data of dissolution for three batches in Phosphate Buffer pH 6.8 as dissolution medium before issuance of registration letter.	
202	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	(VA5-3V3-T69D, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-15,
	The proposed proprietary name / brand name	**Cloviz Cream**
	Label Claim	Each gram contains: Clotrimazole ..... 1%w/w Hydrocortisone 1%w/w
	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)	Hydrozole cream
	Pharmacotherapeutic Group of (API)	Anti-Fungal and Anti-Inflammatory
	Name, address of Manufacturing site:	Aksah Pharmaceuticals Pvt Ltd -Plot NO 47,Street NO NS-10 RCCI Rawat Islamabad-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Axasten Extra Cream in DRAP Meeting 354
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
203	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	(JBH-V76-A9VG, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-04,

	The proposed proprietary name / brand name	**Crotram 37.5/325mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Paracetamol.....325mg Tramadol Hydrochloride.....37.5mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-De-Controlled,2x10's,-De-Controlled,3x10's-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30C Degree
	For generic drugs (me-too Status)	Tonoflex-P Tablet, Sami Pharmaceuticals (Pvt.) Ltd. Karachi
	Pharmacotherapeutic Group of (API)	Analgesic/ Opioid Analgesic
	Name, address of Manufacturing site:	WORLD BIZ PHARMACEUTICALS-Plot No. 340, Industrial Estate,Phase-II, Multan.-
	The status in reference regulatory authorities	Tramadol/Paracetamol 37.5mg / 325mg tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) MHRA Approved.
	Detail of previous approval	M-344 of Registration Board, Reg#129956
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
204	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Ferozsons Laboratories Limited** PO Ferozsons, Amangarh **(000038)**
	Application Form Dy. No / Tracking ID & date of submission	(W1B-QUD-MT3N, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-31,
	The proposed proprietary name / brand name	**Azenta Infusion 500mg**
	Label Claim	Each lyophilized vial contains: Azithromycin Dihydrate eq. to Azithromycin.....500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's -As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C.
	For generic drugs (me-too Status)	Brand Name: AZOBAR 500 MG INFUSION Manufactured by: M/s BF Biosciences Limited
	Pharmacotherapeutic Group of (API)	Macrolides
	Name, address of Manufacturing site:	M/s BF Biosciences Limited-5-KM, Sunder Raiwind Road, Raiwind, Lahore-
	The status in reference regulatory authorities	Brand Name: Azithromycin 500 mg powder for concentrate for solution for infusion Approval granted to : Kensington Pharma Limited,

	Detail of previous approval	Product Name: AZOBAR 500 MG INFUSION 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 Approved	
205	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	**Valor Pharmaceuticals** Plot No 124/A, Industrial Triangle, Kahuta Road, Islamabad **(000496)**
	Application Form Dy. No / Tracking ID & date of submission	(V4J-UDD-6ZZN, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2023-09-25,
	The proposed proprietary name / brand name	**Glifmet 5/1000mg**
	Label Claim	Each film coated compressed tablet contains..... Empagliflozin 5mg . ----------Metformin HCl `1000
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's-As per SRO
	Shelf Life (Unit)	2 YearControlled room temperature
	For generic drugs (me-too Status)	Diampa-M 5/1000 mg
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Empagliflozin,Metfromin HCl
	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	US FDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved. The applicant shall submit fee for revision of specification and data of dissolution for three batches in Phosphate Buffer pH 6.8 as dissolution medium before issuance of registration letter.	

206	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	(9BD-AQ9-B6PQ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-30,
	The proposed proprietary name / brand name	**Comforta 5 mg Tablets**
	Label Claim	Each film coated tablet contains: Cyclobenzaprine Hydrochloride 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30ºC
	For generic drugs (me-too Status)	Eumytic 5mg Tablet
	Pharmacotherapeutic Group of (API)	Skeletal muscle relaxant
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL -Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	Cyclobenzaprine Hydrochloride
	Detail of previous approval	Iciric 5 mg Tablet, DRB M-329
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
207	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	(QQ1-527-SLX2, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-30,
	The proposed proprietary name / brand name	**Dexbro XR 45/105 mg Tablet**
	Label Claim	Each film coated bilayer extended release tablet contains: Dextromethorphan Hydrobromide (as Immediate release layer) .....45mg Bupropion Hydrochloride (as extended release layer) 105mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30ºC
	For generic drugs (me-too Status)	Dexsero XR 45mg/105mg Tablet

	Pharmacotherapeutic Group of (API)	Antidepressants
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL -Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	AUVELITY XR 45MG/105MG TABLET
	Detail of previous approval	Dexsero 45/105 mg XR Tablet, 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 Approved	
208	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Medisynth Pharmaceuticals** Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar Khan, District Rawalpindi **(000718)**
	Application Form Dy. No / Tracking ID & date of submission	(T15-746-T2SL, 2026-03-02)
	Detail of Fee Submitted	97200, 2026-02-25,
	The proposed proprietary name / brand name	**lomezole 40mg**
	Label Claim	Each Vial Contains: Omeprazole (as sodium)....40mg Lyophilised powder
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	24 Month15c-30c
	For generic drugs (me-too Status)	Omezk Injection by BioNext
	Pharmacotherapeutic Group of (API)	Data already approved in 327th meeting
	Name, address of Manufacturing site:	Bio-Lab Pvt Ltd-Plot no 145 kahuta industrial area Islamabad-
	The status in reference regulatory authorities	MHRA/EMA
	Detail of previous approval	omezka injection 40mg 327th meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	

209	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	(NGD-ZXJ-WG2D, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-30,
	The proposed proprietary name / brand name	**SCF 1G/5ML ORAL SUSPENSION**
	Label Claim	Each 5ml of oral suspension contains: Sucralfate 1g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30ºC
	For generic drugs (me-too Status)	Ulsanic 1g/5ml Suspension
	Pharmacotherapeutic Group of (API)	Gastrointestinal tract and metabolism; anti-peptic ulcer and gastroesophageal reflux disease.
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL -Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	ANTEPSIN 1g/5ml Suspension
	Detail of previous approval	Sucraph I g/5ml Oral Suspension, DRB 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 Approved	
210	Case Category	Routine (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(RA1-YGH-LQHP, 2024-10-25)
	Detail of Fee Submitted	37000.0, 2024-10-11,
	The proposed proprietary name / brand name	**EMPAC-LM XR 10mg/5mg/1000mg**
	Label Claim	Each Film Coated Tablet contains: Empagliflozin.....10mg Linagliptin.....5mg (as Immediate release coating) Metformin HCl.....1000mg (as Extended release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 °C
	For generic drugs (me-too Status)	Trilin XR 10+5+1000 mg tablet (PharmEvo Private Limited)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti Drugs Limited ,Anhui Haikang Pharmaceutical Co. Ltd. ,Fuxin Long Rui 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	TRIJARDY XR 10mg/5mg/1000mg TABLET (Boehringer Ingelheim Germany)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
211	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	(RTL-1T9-HVZ8, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-15,
	The proposed proprietary name / brand name	**Omnia 40 mg Injection**
	Label Claim	Each vial contains: Omeprazole sodium equ. to Omeprazole..... 40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30ºC
	For generic drugs (me-too Status)	Ruling 40mg Injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Name, address of Manufacturing site:	Swera Pharmaceuticals -Plot No. 27, Street No. S-4, Industrial Area, Rawat. -
	The status in reference regulatory authorities	Omeprazole 40mg powder for solution for infusion
	Detail of previous approval	Swepra Injection 40 mg, M-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 Approved	
212	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	(HXV-ZBT-QBE3, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-15,
	The proposed proprietary name / brand name	**Esonom 40 mg Injection**
	Label Claim	Each vial contains: Esomeprazole sodium eq. to Esomeprazole..... 40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30ºC
	For generic drugs (me-too Status)	Koncept 40mg Injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Name, address of Manufacturing site:	Swera Pharmaceuticals -Plot No. 27, Street No. S-4, Industrial Area, Rawat. -
	The status in reference regulatory authorities	Nexium I.V 40mg Injection
	Detail of previous approval	Sezro 40 mg Injection, M-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 Approved	
213	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**gulfpharmaceuticals** Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. **(000750)**
	Application Form Dy. No / Tracking ID & date of submission	(2PR-Q32-5M43, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-09,
	The proposed proprietary name / brand name	**Laxmark**
	Label Claim	Each capsule contains sustained release pellets of: Mebeverine HCl.....200mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore belove 30C

	For generic drugs (me-too Status)	Mebever MR of Getz Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antispasmodic
	Name, address of Manufacturing site:	Qadir Pharmaceuticals-Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan-
	The status in reference regulatory authorities	Colofac MR 200mg Modified Release capsules, hard EMC; Mylan Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL
	Detail of previous approval	Mebqad 200mg capsule in 333rd meeting of RB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
214	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**gulfpharmaceuticals** Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. **(000750)**
	Application Form Dy. No / Tracking ID & date of submission	(6XW-BS8-9DVM, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-07,
	The proposed proprietary name / brand name	**I-FER**
	Label Claim	Each 10ml vial contains:- Iron as ferric carboxymaltose 500mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore belove 30C
	For generic drugs (me-too Status)	FERINJECT of RG Pharmaceuticals
	Pharmacotherapeutic Group of (API)	iron preparation
	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	UK MHRA
	Detail of previous approval	Ferrina injection 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 Approved	
215	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**gulfpharmaceuticals** Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. **(000750)**
	Application Form Dy. No / Tracking ID & date of submission	(4VQ-P87-7M94, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-30,
	The proposed proprietary name / brand name	**Evoase**
	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 YearStore belove 30C
	For generic drugs (me-too Status)	ETOXIB 60MG TABLET
	Pharmacotherapeutic Group of (API)	NSAID
	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	UK MHRA ETORICOXIB 60mg TABLET
	Detail of previous approval	Rtiroxx 60mg in 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 Approved	
216	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**gulfpharmaceuticals** Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. **(000750)**
	Application Form Dy. No / Tracking ID & date of submission	(Y9H-2MN-DUAP, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-02,
	The proposed proprietary name / brand name	**G-Mero**
	Label Claim	Each vial contains: Meropenem trihydrate USP eq. to Meropenem.....1g Each vial contains 208 mg sodium carbonate approximately 4.0 mmol of sodium (approximately 90 mg).
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore belove 30C
	For generic drugs (me-too Status)	Merrem injection of Global
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Name, address of Manufacturing site:	Dew-max Pharmaceuticals (Pvt) Ltd.-Plot No.6 Street SS-4 Main Industrial Area Rawat, Islamabad-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	312th Dewnem
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
217	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**gulfpharmaceuticals** Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. **(000750)**
	Application Form Dy. No / Tracking ID & date of submission	(2D8-9WQ-VE7M, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-30,
	The proposed proprietary name / brand name	**Evoase**
	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 YearStore belove 30C
	For generic drugs (me-too Status)	ETOXIB 90MG TABLET
	Pharmacotherapeutic Group of (API)	NSAID
	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	UK MHRA ETORICOXIB 90mg TABLET
	Detail of previous approval	Rtiroxx 90mg in 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 Approved	
218	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**gulfpharmaceuticals** Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. **(000750)**
	Application Form Dy. No / Tracking ID & date of submission	(HZ4-D1M-7V2R, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-02,
	The proposed proprietary name / brand name	**G-Mero**
	Label Claim	Each vial contains: Meropenem trihydrate USP eq. to Meropenem.....500mg Each vial contains 104 mg sodium carbonate which equates to approximately 2 mEq of sodium (approximately 45 mg)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore belove 30C
	For generic drugs (me-too Status)	Merrem injection of Global
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Name, address of Manufacturing site:	Dew-max Pharmaceuticals (Pvt) Ltd.-Plot No.6 Street SS-4 Main Industrial Area Rawat, Islamabad-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	312th Dewnem
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
219	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	(E7J-ZJV-G23H, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-03-05,
	The proposed proprietary name / brand name	**Coside 50 mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Lacosamide.....50mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14'S-Controlled
	Shelf Life (Unit)	2 YearROOM CONDITION
	For generic drugs (me-too Status)	Lecolip 50 mg tablets, Hilton Pharma
	Pharmacotherapeutic Group of (API)	AntiCosideic agent
	Name, address of Manufacturing site:	QADIR PHARMACEUTICALS Pvt. Limited- 6-km, G.T, Road, Wazirabad Sialkot, Pakistan-
	The status in reference regulatory authorities	DRAP
	Detail of previous approval	Minutes of 336th meeting of Registration Board (4th to 6th June, 2024)
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
220	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**gulfpharmaceuticals** Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. **(000750)**
	Application Form Dy. No / Tracking ID & date of submission	(1EP-JU6-Q624, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-30,
	The proposed proprietary name / brand name	**Evoase**
	Label Claim	Each film coated tablet contains Etoricoxib 120mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Starcox 120MG TABLET
	Pharmacotherapeutic Group of (API)	NSAID
	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	UK MHRA
	Detail of previous approval	Rtiroxx 120mg in 339th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
221	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	(VWS-DHN-WLDY, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-03-05,
	The proposed proprietary name / brand name	**Coside 100 mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Lacosamide.....100mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14'S-Controlled
	Shelf Life (Unit)	2 YearROOM CONDITION
	For generic drugs (me-too Status)	Licolep 100 mg Tablets, Hilton Pharma)Pvt) Limited
	Pharmacotherapeutic Group of (API)	AntiCosideic agent
	Name, address of Manufacturing site:	QADIR PHARMACEUTICALS Pvt. Limited-Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan-
	The status in reference regulatory authorities	DRAP
	Detail of previous approval	
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
222	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**gulfpharmaceuticals** Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. **(000750)**
	Application Form Dy. No / Tracking ID & date of submission	(1D1-XH4-VYDD, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-03,

	The proposed proprietary name / brand name	**Bet-G**
	Label Claim	Each gam contains; Betamethasone Dipropionate Eq to Betamethasone.....0.5mg (0.05% w/w) Gentamicin Sulphate Eq to Gentamicin.....1mg (0.1 %w/w)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	15g-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Betagenic cream of Atco
	Pharmacotherapeutic Group of (API)	Corticosteroids, dermatological preparations; Corticosteroids, potent, combinations with antibiotics ATC Code: D07CC01
	Name, address of Manufacturing site:	Focus & Rulz Pharmaceuticals Pvt Ltd-44-Industrial Triangle Area Kahuta Road Islamabad Pakistan-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Betarulz cream in 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 Approved	
223	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	(S6N-MG7-2APN, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-03-05,
	The proposed proprietary name / brand name	**Pridosul 25 mg Tablet**
	Label Claim	Each Tablet Contains: Levosulpiride.....25MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20'S-Controlled,30'S-Controlled,50's-Controlled
	Shelf Life (Unit)	2 YearROOM CONDITION
	For generic drugs (me-too Status)	Levopraid 25 mg Tablets, Pacific Pharmaceutical limited
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Name, address of Manufacturing site:	QADIR PHARMACEUTICALS Pvt. Limited-Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan-
	The status in reference regulatory authorities	DRAP
	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 decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
224	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	(543-ASY-2T49, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-04-01,
	The proposed proprietary name / brand name	**Auvogest 10mg**
	Label Claim	Each film coated tablet contains 10 mg of dydrogesterone
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20'S-As per SRO,30'S-As per SRO
	Shelf Life (Unit)	2 YearRoom Condition
	For generic drugs (me-too Status)	DUPHASTON 10 MG FILM-COATED TABLETS
	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 Sheikhupura Road Lahore.-
	The status in reference regulatory authorities	DRAP
	Detail of previous approval	Minutes of 336th meeting of Registration Board (4th to 6th June, 2024)
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	

225	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	(9P5-73W-H4AZ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-04-01,
	The proposed proprietary name / brand name	**Feritik 500mg**
	Label Claim	Each ml Contains: Ferric carboxymaltose Equivalent to Elemental Iron.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10-As per SRO
	Shelf Life (Unit)	2 YearRoom Condition
	For generic drugs (me-too Status)	Ferinject 50mg/ml Injection M/s Vifor Pharma MHRA Approved
	Pharmacotherapeutic Group of (API)	iron replacement product
	Name, address of Manufacturing site:	Skywin????Pharmaceutical-Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road-
	The status in reference regulatory authorities	DRAP
	Detail of previous approval	Medifer 50mg/1ml Injection. Minutes of 347th meeting of Registration Board (28th – 30th April, 2025)
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
226	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	(LEY-WMM-GBST, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-04-01,
	The proposed proprietary name / brand name	**MIROBUR 2.5MG TAB**
	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	1x10-As per SRO,2x10's-As per SRO,2x7's-As per SRO

	Shelf Life (Unit)	2 YearRoom Condition
	For generic drugs (me-too Status)	Tarlige Tablets 2.5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd-129-Sunder Industrial Estate, Lahore(000789)-
	The status in reference regulatory authorities	DRAP
	Detail of previous approval	Mirogab 2.5mg Tablet, Minutes of 344th meeting of Registration Board (31st December, 2024 – 02nd Jan
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
227	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	(3VP-VSN-LN8Y, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-04-01,
	The proposed proprietary name / brand name	**MIROBUR 5MG TAB**
	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	1x10-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 YearRoom Condition
	For generic drugs (me-too Status)	Tarlige Tablets 5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd-129-Sunder Industrial Estate, Lahore(000789)-
	The status in reference regulatory authorities	DRAP
	Detail of previous approval	Mirogab 5mg Tablet; Minutes of 344th meeting of Registration Board (31st December, 2024 – 02nd Janua
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant	

	application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
228	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(W35-SYT-53MN, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-04-09,
	The proposed proprietary name / brand name	**Delpex**
	Label Claim	Each gram of cream contains: Delgocitinib.....20mg (2.0%) (As per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm 15gm 20gm 30gm-As per SRO
	Shelf Life (Unit)	2 YearStore at 20°C to 25°C .
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Gansu Haotian Pharmaceutical Technology Co., Ltd. Address: No. 11 Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	354
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
229	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hisun Pharmaceutical Industries** 37-A, R-2 Industrial Estate Gadoon, Amazi **(000624)**
	Application Form Dy. No / Tracking ID & date of submission	(DWM-54A-98BN, 2026-08-20)

	Detail of Fee Submitted	97200, 2026-06-09,
	The proposed proprietary name / brand name	**Olopin Eye Drops**
	Label Claim	Each ml contains: Olopatadine as HCl .....2mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Ocudine Eye Drops Reg. No. 067448 by Barret Hodgson Pharma
	Pharmacotherapeutic Group of (API)	Anti Histamine
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE Super Highway, Phase-II, Karachi-
	The status in reference regulatory authorities	Registration Status = Registered by FDA Registration Company = Novartis Pharmaceutical
	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 Approved	
230	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hisun Pharmaceutical Industries** 37-A, R-2 Industrial Estate Gadoon, Amazi **(000624)**
	Application Form Dy. No / Tracking ID & date of submission	(JTY-DPT-3BWV, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-09,
	The proposed proprietary name / brand name	**Lotisun Eye Drops**
	Label Claim	Each ml of ophthalmic suspension contains: Loteprednol Etabonate.....5mg Tobramycin .....3mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Lotetob Opthalmic Suspension by Helix Pharma Reg. No. 092853
	Pharmacotherapeutic Group of (API)	Antibiotic/ Corticosteriods
	Name, address of Manufacturing site:	Winthrox Laboratories (Pvt.) Ltd -K-219-A, SITE Super Highway, Phase-II, Karachi-
	The status in reference regulatory authorities	Zylet Eye Drops approved by USFDA
	Detail of previous approval	Lotinon Eye Drops Approved in 333rd 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 Approved	
231	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hisun Pharmaceutical Industries** 37-A, R-2 Industrial Estate Gadoon, Amazi **(000624)**
	Application Form Dy. No / Tracking ID & date of submission	(P3S-7HR-BT99, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-09,
	The proposed proprietary name / brand name	**Nepawin Eye Drops**
	Label Claim	Each ml of suspension contains: Nepafenac.....1mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Nepanac Ophthalmic Suspension by Remington Pharma Reg. No. 069177
	Pharmacotherapeutic Group of (API)	NSAIDs
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE Super Highway, Phase-II, Karachi-
	The status in reference regulatory authorities	Registered by MHRA Novartis Pharmaceutical, Canada.
	Detail of previous approval	Nepton Eye Drops approved in 333rd 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 Approved	
232	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hisun Pharmaceutical Industries** 37-A, R-2 Industrial Estate Gadoon, Amazi **(000624)**

	Application Form Dy. No / Tracking ID & date of submission	(22X-DS8-G5EW, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-09,
	The proposed proprietary name / brand name	**Ondensen Syrup**
	Label Claim	Each 5ml contains: Ondansetron Hydrochloride Dihydrate eq. to Ondansetron.....4mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Onseron Syrup Indus Pharma, Pakistan 058677
	Pharmacotherapeutic Group of (API)	Antiemetic
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE Super Highway, Phase-II, Karachi-
	The status in reference regulatory authorities	ONDANSETRON SYRUP Registered by ADVANZ PHARMA, UK
	Detail of previous approval	Ondesty Syrup Approved 331st Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
233	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hisun Pharmaceutical Industries** 37-A, R-2 Industrial Estate Gadoon, Amazi **(000624)**
	Application Form Dy. No / Tracking ID & date of submission	(SGE-21G-W946, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-09,
	The proposed proprietary name / brand name	**Moxisun Eye Drops**
	Label Claim	Each ml contains: Moxifloxacin as HCl .....5mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Vigamox Eye Drops by Helix Pharma Reg. No. 093920
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE Super Highway, Phase-II, Karachi-
	The status in reference regulatory authorities	Registered by MHRA UK by Novartis Pharma
	Detail of previous approval	Moxon Eye Drops Approved in 339th Meeting of DRAP

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
234	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	(6HZ-TZU-PS4A, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-04-03,
	The proposed proprietary name / brand name	**Capriz 1.5 mg Capsule**
	Label Claim	Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine..... 1.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30ºC
	For generic drugs (me-too Status)	Caripz 1.5mg Capsule
	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.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 1, Al Badar Industrial Estate, Phase-II, Sheikhupura, Road, Lahore-
	The status in reference regulatory authorities	VRAYLAR (cariprazine) 1.5mg capsules
	Detail of previous approval	Carip 1.5 mg Capsule, M-343
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	

235	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	(QG5-8VW-5J31, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-04-03,
	The proposed proprietary name / brand name	**Capriz 3 mg 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 YearBelow 30ºC
	For generic drugs (me-too Status)	Caripz 3 mg Capsule
	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.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al Badar Industrial Estate, Phase-II, Sheikhupura, Road, Lahore-
	The status in reference regulatory authorities	VRAYLAR (cariprazine) 3mg capsules
	Detail of previous approval	Carip 3 mg Capsule, M-343
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
236	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	(P1T-1D5-B1WX, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-04-03,
	The proposed proprietary name / brand name	**Napzole 500mg/20 mg Tablet**
	Label Claim	Each Modified release tablet contains: Naproxen..... . 500mg (Enteric coated core) Esomeprazole as

		magnesium trihydrate..... 20mg(Immediate released coat)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30ºC
	For generic drugs (me-too Status)	Glomov 500mg/20mg Tablet
	Pharmacotherapeutic Group of (API)	Naproxen belongs to a class of drugs NSAIDS. Esomeprazole belongs to a class of drugs Proton Pump Inhibitor.
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) Limited -Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore -
	The status in reference regulatory authorities	Vimovo 500/20mg modified-release tablet
	Detail of previous approval	Napsom 20/500 mg Tablet, M-331
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
237	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Jinnah Pharmaceuticals Pvt Ltd** 13 Km Lahore Road Multan **(000578)**
	Application Form Dy. No / Tracking ID & date of submission	(X34-J99-HP5N, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**Thiovex 4mg**
	Label Claim	Each Capsule contains Thiocolchicoside ..... 4mg As per innovator's Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30%
	For generic drugs (me-too Status)	Thioget 4mg Capsule of M/s. Getz Pharma (Reg.no.086076)
	Pharmacotherapeutic Group of (API)	Muscle relaxant
	Name, address of Manufacturing site:	Carer Pharmaceuticals Industries-Plot No. 27 main road, RCCI Industrial Estate Rawat Islamabad-
	The status in reference regulatory authorities	ANSM
	Detail of previous approval	CPLAX 4mg Capsule Reg No 135703 DRB Meeting M-357
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
238	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	(4ET-HSX-D279, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-04-14,
	The proposed proprietary name / brand name	**Ontron 4mg/5ml Syrup**
	Label Claim	Each 5ml contains: Ondansetron as Hydrochloride Dihydrate.....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml amber glass bottle-Controlled,25ml amber glass bottle-Controlled,50ml amber glass bottle-Controlled
	Shelf Life (Unit)	2 YearStore at 25°C (Excursions permitted between 15°C - 30°C).
	For generic drugs (me-too Status)	Onset 4mg/5ml Syrup by M/s Pharmedic (Pvt) Ltd. Registration number:025996
	Pharmacotherapeutic Group of (API)	Antiemetic
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore, Pakistan-
	The status in reference regulatory authorities	MHRA Approved (4mg/5ml)
	Detail of previous approval	Stawia 4mg/5ml Syrup in 326 Registration Board Meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
239	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	(9J8-6B6-R8HT, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**Moistane 0.4%/0.3% Eye Drops**
	Label Claim	Each ml contins: Polyethylene glycol 400....4mg Propylene Glycol .... 3mg (Innovator's specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	15ml-As per SRO
	Shelf Life (Unit)	2 Year15C-25C
	For generic drugs (me-too Status)	Ropsol Eye Drops by ATCO Labs
	Pharmacotherapeutic Group of (API)	Ophthalmic lubricant
	Name, address of Manufacturing site:	MEDEVO (PRIVATE) LTD.-Plot no. 94 Sunder industrial Estate Raiwind, Lahore-
	The status in reference regulatory authorities	Systane by Alcon Laboratories, Inc.
	Detail of previous approval	Evosys 0.4%/0.3% Eye drops- 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 Approved	
240	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	(GA7-GXM-EG91, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**Torcin 0.3% Eye Drops**
	Label Claim	Each ml contains: Tobramycin ... 3mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 Year15C-25C
	For generic drugs (me-too Status)	Tobracin Eye Drops by Helix Pharma
	Pharmacotherapeutic Group of (API)	aminoglycoside group of antibiotics
	Name, address of Manufacturing site:	MEDEVO (PRIVATE) LTD.-Plot no. 94 Sunder industrial Estate Raiwind, Lahore-
	The status in reference regulatory authorities	TGA- TOBREX by Novartis
	Detail of previous approval	Evotob 0.3% Eue drops - M336

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
241	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	(P1D-GMV-Z4A6, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-22,
	The proposed proprietary name / brand name	**Ompalin 40mg Injection**
	Label Claim	Each lyophilized vial contains: Omeprazole sodium equivalent to Omeprazole... 40mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 x 1's-As per SRO
	Shelf Life (Unit)	24 Month15C - 25C
	For generic drugs (me-too Status)	Omea injection 40mg IV by Nionext Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors (PPIs). Chemically, it is classified as a substituted benzimidazole
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot No. 145, Industrial Triangle, kahuta Road, Islamabad, Pakistan-
	The status in reference regulatory authorities	Omeprazole 40mg powder for Injection by Sandoz A Novartis Divission.
	Detail of previous approval	Omevex 40mg Injection (M-324), previously named as Omezka
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
242	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	(XPU-LAS-UPRJ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-04-16,
	The proposed proprietary name / brand name	**CEFBACT 2000 MG INJ**
	Label Claim	Each vial contains: Sterile Powder of Cefoperazone.....1000mg Sulbactam.....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearRoom Condition
	For generic drugs (me-too Status)	Cefbac Inj by Seraph Pharmaceutical
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Name, address of Manufacturing site:	Shawan Pharmaceuticals-Plot No. 37, Road NS 1, National Industrial Zone, RCCI Rawat, Islamabad, Pakistan-
	The status in reference regulatory authorities	DRAP
	Detail of previous approval	Q-Dux 2000mg Inj. 330th meeting of Registration Board (24th to 26th July, 2023)
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
243	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	(SJB-8AQ-NBH5, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**Loterex-T 0.5%/0.3% Eye Drops**
	Label Claim	Each ml contains; Loteprenol etabonate...5mg Tobramycin...3mg Innovator's specs
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 Year15C-25C
	For generic drugs (me-too Status)	LOTEPRED-T ophthalmic Suspension by Sante

	Pharmacotherapeutic Group of (API)	corticosteroid and aminoglycoside antibiotic combination
	Name, address of Manufacturing site:	MEDEVO (PRIVATE) LTD.-Plot no. 94 Sunder industrial Estate Raiwind, Lahore-
	The status in reference regulatory authorities	USFDA- LOTEPRED-T ophthalmic Suspension
	Detail of previous approval	Medilot-T eye Drops- M336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
244	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	(UHN-W25-Y72U, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**Moxin 0.5% Eye Drops**
	Label Claim	Each ml contains: Moxifloxacin HCl eq. to Moxifloxacin. 5mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 Year15C-25C
	For generic drugs (me-too Status)	Moxigan (0.5%) 5Ml Eye Drops by Barrett Hodgson
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotics
	Name, address of Manufacturing site:	MEDEVO (PRIVATE) LTD.-MEDEVO (PRIVATE) LTD. Plot No. 94, Sundar Industrial Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Moxivig by Novartis, MHRA, UK.
	Detail of previous approval	Evomox 0.5% eye drops- 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	

	Approved	
245	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	(N8Q-R5Z-5D35, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**Torcin-D 0.3%/0.1% Eye Drops**
	Label Claim	Each ml contains Tobramycin.....3 mg Dexamethasone .....1 mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 Year15C-25C
	For generic drugs (me-too Status)	Tobradex 0.1%/0.3% eye drop by Novartis
	Pharmacotherapeutic Group of (API)	Tobramycin is an aminoglycoside antibiotic & Dexamethasone is a corticosteroid
	Name, address of Manufacturing site:	MEDEVO (PRIVATE) LTD.-MEDEVO (PRIVATE) LTD. Plot No. 94, Sundar Industrial Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	USFDA- TOBRADEX Eye Drop by Novartis
	Detail of previous approval	Evotob-D 0.3%/ 0.1% eye drops- M 335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
246	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	(N99-4D3-7QNB, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-22,
	The proposed proprietary name / brand name	**Makzo 40mg Injection**
	Label Claim	Each lyophilized vial contains: Esomeprazole as Sodium .... 40mg (BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 x 1's-As per SRO
	Shelf Life (Unit)	24 Month15C - 25C
	For generic drugs (me-too Status)	Nexum injection 40mg IV by GETZ

	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors (PPIs). Chemically, it is classified as a substituted benzimidazole
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot No. 145, Industrial Triangle, kahuta Road, Islamabad, Pakistan-
	The status in reference regulatory authorities	Nexium 40mg Injection of M/s Astrazeneca (USFDA approved)
	Detail of previous approval	Esomezka 40mg IV Injection (M-331)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
247	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	(EEL-AV9-J2W5, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-11,
	The proposed proprietary name / brand name	**Sevla-C 800mg Tablet**
	Label Claim	Each film coated tablet contains: Sevelamer Carbonate .... 800mg (As per Innovator's specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 Year15C - 25C
	For generic drugs (me-too Status)	Renavel 800mg TABLET
	Pharmacotherapeutic Group of (API)	phosphate binder (or phosphate-removing agent
	Name, address of Manufacturing site:	WNSFEILD Pharmaceuticals, -WNSFEILD Pharmaceuticals, PLOT NO.122, PHASE-V, BLOCK-A, INDUSTRIAL ESTATE, HATTAR, KPK, PAKISTAN. -
	The status in reference regulatory authorities	Sevelamer carbonate 800mg Tablet by Zentiva pharma uk limited
	Detail of previous approval	Savelo 800mg Tablet- M340
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved Approved	
248	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	(RHQ-J44-QYRQ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**Nepagen 0.1% Eye Drops**
	Label Claim	Each ml contains: Nepafenac...1mg (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 Year15C-25C
	For generic drugs (me-too Status)	NEVANAC Eye Drop by Novartis pharmaceuticals
	Pharmacotherapeutic Group of (API)	NSAID.
	Name, address of Manufacturing site:	MEDEVO (PRIVATE) LTD.-Plot no. 94 Sunder industrial Estate Raiwind, Lahore-
	The status in reference regulatory authorities	MHRA, UK. NEVANAC Eye Drop by Novartis pharmaceuticals
	Detail of previous approval	Evonap 0.1% Opthalmic suspension- M 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
249	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	(YVP-WXV-LPAZ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**Nepagen TS 0.3% Eye Drops**
	Label Claim	Each ml contains; Nepafenac... 3mg (Innovator's specs)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	3ml-As per SRO
	Shelf Life (Unit)	2 Year15C-25C
	For generic drugs (me-too Status)	NEVANAC Eye Drop by Novartis pharmaceuticals
	Pharmacotherapeutic Group of (API)	NSAID.
	Name, address of Manufacturing site:	MEDEVO (PRIVATE) LTD.-Plot no. 94 Sunder industrial Estate Raiwind, Lahore-
	The status in reference regulatory authorities	MHRA, UK. NEVANAC Eye Drop by Novartis pharmaceuticals
	Detail of previous approval	Evonap-Forte 0.3% opthalmic suspension- M331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
250	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	(35J-GNW-Z32T, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**Patalon-DS 0.2% Eye Drops**
	Label Claim	Each ml contains: Olopatadine HCl eq. to Olopatadie... 2mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 Year15C-25C
	For generic drugs (me-too Status)	Winolap Eye Drops 0.2% by ATCO Laboratories
	Pharmacotherapeutic Group of (API)	antihistamine and mast cell stabilizer
	Name, address of Manufacturing site:	MEDEVO (PRIVATE) LTD.-Plot no. 94 Sunder industrial Estate Raiwind, Lahore-
	The status in reference regulatory authorities	PATADAY Ophthalmic Solution by Alcon Laboratories, USFDA.
	Detail of previous approval	MedipAt-DS 0.2% Eye Drops- 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 Approved	
251	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	(HTX-7ZE-A3AE, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**Loterex 0.5% Eye Drops**
	Label Claim	Each ml contains: Loteprednl Etabonate.... 5mg (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 Year15C-25C
	For generic drugs (me-too Status)	Lotepred forte Ophthalmic Suspension by Sante
	Pharmacotherapeutic Group of (API)	corticosteroid group
	Name, address of Manufacturing site:	MEDEVO (PRIVATE) LTD.-Plot no. 94 Sunder industrial Estate Raiwind, Lahore-
	The status in reference regulatory authorities	USFDA, Lotepred forte Ophthalmic Suspension by SANTE PRIVATE LIMITED
	Detail of previous approval	Medilot 0.5% Eye Drops- 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 Approved	
252	Case Category	Export Facilitation (Incharge Evaluation Cell)
	Name, address of Applicant.	**SKIMS PHARMACEUTICALS** 10/B VALUE ADDITION CITY,KHURRIANWALA **(000830)**
	Application Form Dy. No / Tracking ID & date of submission	(H2Q-HXW-TS26, 2025-03-04)
	Detail of Fee Submitted	37000.0, 2025-01-23,
	The proposed proprietary name / brand name	**Terbikim 250mg Tablet**
	Label Claim	Each Tablet Contains: Terbinafine HCl eq. To Terbinafine .... 250mg (Product complies with USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled

	Shelf Life (Unit)	3 Year(s)Store below 30 degree. Protect from light, moisture and heat.
	For generic drugs (me-too Status)	Terbiderm Forte Tablets
	Pharmacotherapeutic Group of (API)	D01BA02 for systemic use; antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of three batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Terbiderm forte Tablets manufactured by ATCO Karachi
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at long term and accelerated conditions
	The status in reference regulatory authorities	Lamisil -FDA approved
	GMP status of the firm	GMP report dated 10.10.2023
	Evidence of approval of manufacturing facility	Renewal of DML No 000830 dated 09.05.2024
	Evaluation Remarks	
	Export Facilitation	
	Decision	
	Approved	
253	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	(BLA-GY7-DWXU, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-04-15,
	The proposed proprietary name / brand name	**Oniron ODT 8mg Tablet**
	Label Claim	Each Orodispersible tablet contains: Ondansetron..... 8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30ºC
	For generic drugs (me-too Status)	Dysit ODT 8mg Tablet
	Pharmacotherapeutic Group of (API)	Ondansetron is used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy, and surgery. Ondansetron is in a class of medications called serotonin 5-HT3 receptor antagonists. It works by blocking the action of serotonin, a natural substance that may cause nausea and vomiting.
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) Limited -Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore -
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	Only Module-I Required
	Documents for the procurement of API with approval from DRAP	Only Module-I Required

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Only Module-I Required
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Only Module-I Required
	The status in reference regulatory authorities	Ondansetron Bluefish 8mg orodispersible tablets
	GMP status of the firm	Attached with Module-I
	Evidence of approval of manufacturing facility	Attached with Module-I
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
254	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	(WPB-BY5-JY45, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-16,
	The proposed proprietary name / brand name	**Resmiter**
	Label Claim	Each Film Coated Tablet contains: Resmetirom .....80 mg
	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 Year Store at 20 °C to 25°C
	For generic drugs (me-too Status)	Getz Pharma Private Ltd (Resmetirom)
	Pharmacotherapeutic Group of (API)	Nantong Chanyoo Pharmatech Co., Ltd
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44-45B Korangi Creek Road karachi -
	The status in reference regulatory authorities	Rezdiffra (UPM Pharmaceuticals (Bristol, TN)
	Detail of previous approval	359th Meeting, Restirom
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved Approved	
255	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	(RV2-SUG-ASEY, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-16,
	The proposed proprietary name / brand name	**Resmiter**
	Label Claim	Each Film Coated Tablet contains: Resmetirom .....100 mg
	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 Year Store at 20 °C to 25°C
	For generic drugs (me-too Status)	Getz Pharma Private Ltd (Resmetirom)
	Pharmacotherapeutic Group of (API)	Nantong Chanyoo Pharmatech Co., Ltd
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44-45B Korangi Creek Road karachi -
	The status in reference regulatory authorities	Rezdiffra (UPM Pharmaceuticals (Bristol, TN)
	Detail of previous approval	359th Meeting, Restirom
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
256	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Obsons Pharmaceuticals** 209-S Quaid-e-Azam industrial estate, **(000416)**
	Application Form Dy. No / Tracking ID & date of submission	(STV-8ZQ-84SS, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-04-30,
	The proposed proprietary name / brand name	**Obgest 10 mg Tablet**
	Label Claim	Each film coated tablet contains: Dydrogesterone 10 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20's-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature
	For generic drugs (me-too Status)	Dydrosky 10 mg Tablet

	Pharmacotherapeutic Group of (API)	Progestogen
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Badar Industrial Estate, Phase II, Sheikhupura Road, Lahore, Pakistan.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Dydrosky 10 mg Tablet. DRB Meeting 336
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
257	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well Care Pharmaceuticals** A/7 PSIE **(000465)**
	Application Form Dy. No / Tracking ID & date of submission	(HQU-JT1-XD4D, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-08,
	The proposed proprietary name / brand name	**Vonocare 20mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: - Vonoprazan Fumarate eq. to Vonoprazan .....20mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x7's; 2x7's; 4x7's; 3x10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30%
	For generic drugs (me-too Status)	VPN-20 Tablet 20mg Manufacturer/Registration holder M/s Helix Pharma (Pvt)., Ltd
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Name, address of Manufacturing site:	MS JINNAH PHARMACEUTICALS. PVT LTD-13-KM Lahore Road Multan-
	The status in reference regulatory authorities	(PMDA Japan Approved)
	Detail of previous approval	Reg No 127757 against our on line application 82T-U2S-P8RM PRVC transfer of manufeaturing to self on CTD
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV vide TID 82T-U2S-P8RM dated 22 December 2025.	
	Decision	

	Approved Approved	
258	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Indus Pharma (Pvt.) Ltd.** Plot No 26,27,63,64,65,66 & 67 Sector 27, Korangi Industrial Area, Karachi. **(000124)**
	Application Form Dy. No / Tracking ID & date of submission	(RMD-G6Z-9S14, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-11,
	The proposed proprietary name / brand name	**Ubro 100mg Tablets**
	Label Claim	Each tablet contains: Ubrogepant Trihydrate eq. to Ubrogepant ..... 100mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,100's-As per SRO,12's-As per SRO,14's-As per SRO,16's-As per SRO,2's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,4's-As per SRO,40's-As per SRO,50's-As per SRO,6's-As per SRO,60's-As per SRO,70's-As per SRO,8's-As per SRO,80's-As per SRO,90's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Ubro 100mg Tablets, By Medizan Laboratories (Approved in 354th DRB Meeting)
	Pharmacotherapeutic Group of (API)	CGRP antagonist
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	UBRELVY (Ubrogepant) tablets (USFDA)
	Detail of previous approval	Ubro 100mg Tablet (Approved in 354th DRB Meeting)
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
259	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**

	Application Form Dy. No / Tracking ID & date of submission	(2LT-AJ4-SHG5, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Trixomap Injection 250 mg (IM)**
	Label Claim	Each Vial Contains: Ceftriaxone (as Sodium) 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C. Do not freeze the recons tituted solution.
	For generic drugs (me-too Status)	Esticef Injection 250mg
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporin antibiotic
	Name, address of Manufacturing site:	M/S Nicholas Pharmaceuticals-Address: Plot # 34, Street No. SS 2, National Industrial Zone, Rawat, Islamabad.-
	The status in reference regulatory authorities	Roche Products Limited, UK
	Detail of previous approval	324th meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV vide TID N9P-EZE-V9AY dated 27 June 2025.	
	Decision	
	Approved Approved	
260	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	(VT9-BYU-B1TR, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-16,
	The proposed proprietary name / brand name	**RESMITER**
	Label Claim	Each Film Coated Tablet contains: Resmetirom .....60 mg
	Reference to Finished product specifications	As per Innovators Specification
	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)	Getz Pharma Pvt Ltd (Resmirom)
	Pharmacotherapeutic Group of (API)	Nantong Chanyoo Pharmatech Co., Ltd
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd-44-45-B,Korangi creek Road Karachi-

	The status in reference regulatory authorities	UPM Pharmaceuticals (Bristol, TN) (Rezdiffra)
	Detail of previous approval	359, Restirom
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
261	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**
	Application Form Dy. No / Tracking ID & date of submission	(GGH-8N6-AEXE, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-08,
	The proposed proprietary name / brand name	**Prugymap 2/0.5mg Tablet**
	Label Claim	Each of the 11 white sugar coated tablets contains: Estradiol Valerate..... 2mg Each of the10 light brown sugar coated tablets contains: Estradiol Valerate..... 2mg Norgestrel 0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 21's , 3x21's As-As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	PROGYLUTON (Estradiol Valerate-Norgestral) TabletofM/sBayerPakistan
	Pharmacotherapeutic Group of (API)	Swati Spentose Private Limited. Manufacturing Facility:A-1/2111,PhaseIII,GIDC,Vapi,396195, Gujarat,India,ZhejiangXianjuJunye PharmaceuticalCo.,Ltd.ManufacturingFacility: No.1LingxiuRoad,ModernIndustrial CentralizationZone,Xianju,Taizhou,Zhejiang, China
	Name, address of Manufacturing site:	M/S SKYWIN PHARMACEUTICAL-PLOT NO. 01/A, BADAR INDUSTRIAL ESTATE, PHASE-II, 18-KM, SHEIKHPURA ROAD LAHORE.-
	The status in reference regulatory authorities	Progyluton Coated Tablet of M/s Bayer Weimar GmbHundCo.KG,Weimar,Germany.
	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 Approved	
262	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**
	Application Form Dy. No / Tracking ID & date of submission	(WXN-MMN-PDHX, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-30,
	The proposed proprietary name / brand name	**ESO-N Tablet**
	Label Claim	Each Film Coated modified release tablet contains Naproxen (as enteric coated core) .....375mg Esomeprazole as magnesium trihydrate as immediate release coat) 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C. Store in the original package in order to protect from light.
	For generic drugs (me-too Status)	Proxen ES DR 375mg /20mg Tablet
	Pharmacotherapeutic Group of (API)	Non-Steroidal Anti-Inflammatory Drug (NSAID) in combination with a Proton Pump Inhibitor (PPI).
	Name, address of Manufacturing site:	M/S CALIPH PHARMACEUTICALS (PVT.) LTD-Plot No. 17, Special Industrial Zone (EPZ), Risalpur-
	The status in reference regulatory authorities	US FDA
	Detail of previous approval	340th Minutes of Meeting, Naspec 375mg + 20mg Tablet
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
263	Case Category	Export Facilitation (Incharge Evaluation Cell)
	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	(HEU-B83-GBV4, 2026-04-02)
	Detail of Fee Submitted	38700, 2026-03-13,
	The proposed proprietary name / brand name	**Famorid Tablets 10mg**
	Label Claim	Each film-coated tablet contains: Famotidine 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x10's, -De-Controlled,1X10's,-De-Controlled,3x10's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30ºC. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Hiler 10mg tablets ; GETZ PHARMA
	Pharmacotherapeutic Group of (API)	H2 receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	--
	Detail of stability batches of drug product	ATTACHED IN 3.2.P.8
	Documents for the procurement of API with approval from DRAP (in case of Import)	K-2186024263542
	Pharmaceutical Equivalence and Comparative Dissolution Profile	attached in 3.2.P.2.2.4
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	attached in 3.2.s.7
	The status in reference regulatory authorities	Pepcid Tablets 10mg; Johnson & Johnson Consumer, Inc, Fort Washington, USA.: https://assets.hpra.ie/products/Human/22266/Licen 032-001_01072024122933.pdf
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	dml no. 000136
	Evaluation Remarks	
	Export Facilitaiton	
	Decision	
	Approved	
264	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**
	Application Form Dy. No / Tracking ID & date of submission	(MHX-TVY-162D, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-08,
	The proposed proprietary name / brand name	**Dopamap 10mg Tablet**
	Label Claim	Each film coated tablet contain: Dydrogesterone 10mg Tablet
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	3 YearBelow 30°C
	For generic drugs (me-too Status)	Duphaston 10mg Film Coated Tablet
	Pharmacotherapeutic Group of (API)	M/s Yangzhou Aurisco Pharmaceutical Co Ltd.

	Name, address of Manufacturing site:	M/S SKYWIN PHARMACEUTICAL-PLOT NO. 01/A, BADAR INDUSTRIAL ESTATE, PHASE-II, 18-KM, SHEIKHPURA ROAD LAHORE.-
	The status in reference regulatory authorities	HPRA
	Detail of previous approval	TABLET D-GEST 10 MG; 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 Approved	
265	Case Category	New Molecule/Formulation (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**
	Application Form Dy. No / Tracking ID & date of submission	(67X-BL1-TW2N, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-08,
	The proposed proprietary name / brand name	**Noremap 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 YearBelow 30°C
	For generic drugs (me-too Status)	Primolut N (Norethisterone) 5mg Tablet of M/s OBS
	Pharmacotherapeutic Group of (API)	M/s Swati Spentose Private Limited Address: A-1/2111, Phase III, GIDC, Vapi, 396 195, Gujarat, India
	Name, address of Manufacturing site:	M/S SKYWIN PHARMACEUTICAL-PLOT NO. 01/A, BADAR INDUSTRIAL ESTATE, PHASE-II, 18-KM, SHEIKHPURA ROAD LAHORE.-
	The status in reference regulatory authorities	Primolut N® 5 mg Tablets
	Detail of previous approval	Just-N 5mgTablet;Minutes of 347th meeting of Registration Board (28th – 30th April, 2025)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
266	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hisun Pharmaceutical Industries** 37-A, R-2 Industrial Estate Gadoon, Amazi **(000624)**
	Application Form Dy. No / Tracking ID & date of submission	(T7W-65D-VRMD, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-11,
	The proposed proprietary name / brand name	**Dydro 10mg Tablet**
	Label Claim	Each film coated tablet contains 10 mg of Dydrogesterone.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Dydrogest 10mg Tablet of M/s OBS Pakistan Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Genito Urinary system and sex hormones.
	Name, address of Manufacturing site:	Skywin Pharmaceutical Pvt. Ltd-Plot # 01, AL Badar Idustrial Estate Phase II, Sheikhupura Road, Sheikhupura Sheikhupura-
	The status in reference regulatory authorities	Duphaston 10 mg film-coated tablets of M/s Mylan IRE Healthcare Limited, Duphaston 10 mg film-coated tablets ® is Approved in HPRA of Ireland.
	Detail of previous approval	D-Gest 10mg Tablet - 336th Meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
267	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	(9PJ-X25-PXXU, 2026-08-20)

	Detail of Fee Submitted	97200, 2026-07-08,
	The proposed proprietary name / brand name	**Mayfer 500mg /10 ml Injection**
	Label Claim	Mayfer 500mg /10 ml Injection 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	10mlx1's-As per SRO,5's-As per SRO
	Shelf Life (Unit)	2 YearStore at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Ferojin 500mg/10ml Injection
	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	FERINJECT (Vifor Pharma Pty Ltd) TGA Approved
	Detail of previous approval	Minutes of 352nd Meeting of Registration Board (19th – 20th November, 2025) Page no.308
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
268	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hisun Pharmaceutical Industries** 37-A, R-2 Industrial Estate Gadoon, Amazi **(000624)**
	Application Form Dy. No / Tracking ID & date of submission	(H3P-V2B-PLS7, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-11,
	The proposed proprietary name / brand name	**N-One 5mg Tablet**
	Label Claim	Each Tablet contains: Norethisterone.....5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Primolut-N Tablet of M/s OBS Pharma Pvt. LTd.
	Pharmacotherapeutic Group of (API)	Norethisterone, also known as norethindrone, is a synthetic progestational hormone belonging to the 19-nortestosterone-derived class of progestins.
	Name, address of Manufacturing site:	Skywin Pharmaceutical Pvt. Ltd-Plot # 01, AL Badar Idustrial Estate Phase II, Sheikhupura Road, Sheikhupura Sheikhupura-

	The status in reference regulatory authorities	Primolut N Tablet 5mg of M/s Bayer plc, 400 South Oak Way, Reading, Berkshire, RG2 6AD (MHRA Approved)
	Detail of previous approval	Just-N 5mg Tablet - 347th Meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
269	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	(ZNY-M9N-S6EN, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-31,
	The proposed proprietary name / brand name	**Veno 10mg Tablet**
	Label Claim	Each film coated tablet contains Vonoprazan fumarate eq. to Vonoprazan ..... 10 mg
	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)	Vonozan Medizan
	Pharmacotherapeutic Group of (API)	Potassium-competitive acid blockers (PCABS).
	Name, address of Manufacturing site:	Medizan Laboratories Pvt. Ltd.-Plot # 313 Industrial Triangle Kahuta road Islamabad Pakistan-
	The status in reference regulatory authorities	PMDA Japan Approved
	Detail of previous approval	M-331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	

270	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hisun Pharmaceutical Industries** 37-A, R-2 Industrial Estate Gadoon, Amazi **(000624)**
	Application Form Dy. No / Tracking ID & date of submission	(DNJ-WHJ-9ZHH, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-11,
	The proposed proprietary name / brand name	**FCM 500mg/10ml Injection**
	Label Claim	Each ml contains: Ferric carboxymaltose Equivalent to Elemental Iron 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 10ml-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	IZER (Ferric carboxymaltose) 500mg/10ml Injection of M/s Pharmasol Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Ferric carboxymaltose injection is in a class of medications called iron replacement products. It works by replenishing iron stores so that the body can make more red blood cells.
	Name, address of Manufacturing site:	Skywin Pharmaceutical Pvt. Ltd-Plot # 01, AL Badar Idustrial Estate Phase II, Sheikhupura Road, Sheikhupura Sheikhupura-
	The status in reference regulatory authorities	Ferinject 50mg/ml Injection of M/s Vifor Pharma (MHRA Approved)
	Detail of previous approval	Medifer 50mg/ml Injection - 347th Meeting
	Evaluation Remarks	
	Decision	
	Approved Approved	
271	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	(6VE-E3S-1EYH, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-31,
	The proposed proprietary name / brand name	**Veno 20mg Tablet**
	Label Claim	Each film coated tablet contains Vonoprazan fumarate eq. to Vonoprazan ..... 20 mg
	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)	Vixozan Medizan
	Pharmacotherapeutic Group of (API)	Potassium-competitive acid blockers (PCABS).
	Name, address of Manufacturing site:	Medizan Laboratories Pvt. Ltd.-Plot # 313 Industrial Triangle Kahuta road Islamabad Pakistan-
	The status in reference regulatory authorities	PMDA Japan approved

	Detail of previous approval	M-331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
272	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	(Y84-NAS-M7Q1, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-30,
	The proposed proprietary name / brand name	**Admont 4mg Sachet**
	Label Claim	Each sachet contains: Montelukast as sodium.....4 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)	Singulair
	Pharmacotherapeutic Group of (API)	Lukotriene Receptor Antagonist (LTRA)
	Name, address of Manufacturing site:	Carer Pharmaceutical Industries-Plot #27, Main Road, Industrial Estate, Rawat-
	The status in reference regulatory authorities	MHRA Approved Drug.
	Detail of previous approval	M-331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
273	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hisun Pharmaceutical Industries** 37-A, R-2 Industrial Estate Gadoon, Amazi **(000624)**
	Application Form Dy. No / Tracking ID & date of submission	(DL1-DBJ-ABXL, 2026-08-20)

	Detail of Fee Submitted	97200, 2026-05-11,
	The proposed proprietary name / brand name	**Mirogab 2.5mg Tablet**
	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	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Miro 2.5mg Tablet of M/s Nabi Qasim
	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot No.129, Sundar Industrial Estate, Riwind Road, Lahore-
	The status in reference regulatory authorities	Tarlige Tablets 2.5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 2.5mg Tablet approved in 344th Meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
274	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hisun Pharmaceutical Industries** 37-A, R-2 Industrial Estate Gadoon, Amazi **(000624)**
	Application Form Dy. No / Tracking ID & date of submission	(LN9-9B2-PSA7, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-11,
	The proposed proprietary name / brand name	**Mirogab 5mg Tablet**
	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	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Miro 5mg Tablet of M/s Nabi Qasim
	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot No.129, Sundar Industrial Estate, Riwind 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 approved in 344th Meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
275	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nortech Pharmaceuticals(Pvt)Ltd** Plot No#203 Sihala Industrial Triangle Kahuta Road,Islamabad **(000792)**
	Application Form Dy. No / Tracking ID & date of submission	(754-NVL-7LRX, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**Venopranor 10mg Tablet**
	Label Claim	Each film coated tablet contains Vonoprazan fumarate eq. to Vonoprazan ..... 10 mg
	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)	Vixozan Medizan
	Pharmacotherapeutic Group of (API)	potassium-competitive acid blockers (PCABs)
	Name, address of Manufacturing site:	Medizan Laboratories Pvt. Ltd.-Plot # 313 Industrial Triangle Kahuta road Islamabad Pakistan-
	The status in reference regulatory authorities	FDA Approved Drug.
	Detail of previous approval	M-331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
276	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nortech Pharmaceuticals(Pvt)Ltd** Plot No#203 Sihala Industrial Triangle Kahuta Road,Islamabad

		(000792)
	Application Form Dy. No / Tracking ID & date of submission	(EMG-GBL-JASB, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**Venopranor 20mg Tablet**
	Label Claim	Each film coated tablet contains Vonoprazan fumarate eq. to Vonoprazan ..... 20 mg
	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)	Vixozan Medizan
	Pharmacotherapeutic Group of (API)	potassium-competitive acid blockers (PCABs)
	Name, address of Manufacturing site:	Medizan Laboratories Pvt. Ltd.-Plot # 313 Industrial Triangle Kahuta road Islamabad Pakistan-
	The status in reference regulatory authorities	FDA Approved Drug.
	Detail of previous approval	M-331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
277	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hisun Pharmaceutical Industries** 37-A, R-2 Industrial Estate Gadoon, Amazi **(000624)**
	Application Form Dy. No / Tracking ID & date of submission	(N3H-5S2-ALDS, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-11,
	The proposed proprietary name / brand name	**Esonap 500/20mg Tablet**
	Label Claim	Each Modified release tablet contains: Naproxen.....500mg (Enteric coated core) Esomeprazole as magnesium trihydrate .....20mg(Immediate released coat)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Glomov 500mg/20mg Tablet of M/s Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Naproxen belongs to a class of drugs NSAIDS. Esomeprazole belongs to a class of drugs Proton

		Pump Inhibitor.
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot No.129, Sundar Industrial Estate, Riwind Road, Lahore-
	The status in reference regulatory authorities	Vimovo 500/20mg modified-release tablet of M/s Grunenthal Ltd (USFDA Approved)
	Detail of previous approval	Napsom 20/500mg Tablet approved in 331st Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
278	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**PERFECT PHARMA (PVT) LTD** 5Km, Manga Road, Raiwind, Lahore **(000469)**
	Application Form Dy. No / Tracking ID & date of submission	(M24-SXX-9DGN, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-09,
	The proposed proprietary name / brand name	**MICRO 15mg Tablet**
	Label Claim	Each film coated tablets contains: Mirogabalin As Besylate 15mg
	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
	Shelf Life (Unit)	2 Year30
	For generic drugs (me-too Status)	Mirogab 15mg Tablet
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Neophar Healthcare Pakistan (Pvt.) Limited-Plot No. 568, Sundar Industrial Estate, Raiwind Road Lahore-
	The status in reference regulatory authorities	Tarlige 15mg Tablets (Mirogabalin), M/s Daiichi Sankyo, Japan
	Detail of previous approval	Numiro 15mg Tablet,Meeting No 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 Approved	
279	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**PERFECT PHARMA (PVT) LTD** 5Km, Manga Road, Raiwind, Lahore **(000469)**
	Application Form Dy. No / Tracking ID & date of submission	(DZ2-SBV-EVNM, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-09,
	The proposed proprietary name / brand name	**MICRO Tablet 2.5mg Tablet**
	Label Claim	Each film coated tablet contains Mirogabalin 2.5mg as Mirogabalin Besylate
	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
	Shelf Life (Unit)	2 Year30
	For generic drugs (me-too Status)	Mirogab 2.5mg Tablet
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Neophar Healthcare Pakistan (Pvt.) Limited-Plot No. 568, Sundar Industrial Estate, Raiwind Road Lahore-
	The status in reference regulatory authorities	Tarlige Tablets (Mirogabalin), M/s Daiichi Sankyo, Japan
	Detail of previous approval	Numiro 2.5mg Tablet, Meeting No 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 Approved	
280	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**PERFECT PHARMA (PVT) LTD** 5Km, Manga Road, Raiwind, Lahore **(000469)**
	Application Form Dy. No / Tracking ID & date of submission	(TBL-ARY-VPS6, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-09,
	The proposed proprietary name / brand name	**MICRO Tablet 10mg Tablet**
	Label Claim	Each film coated tablets contains: Mirogabalin As Besylate 10mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	1x10's-As per SRO,1x7's-As per SRO,2x7's-As per SRO
	Shelf Life (Unit)	2 Year30
	For generic drugs (me-too Status)	Mirogab 10mg Tablet
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Neophar Healthcare Pakistan (Pvt.) Limited-Plot No. 568, Sundar Industrial Estate, Raiwind Road Lahore-
	The status in reference regulatory authorities	Tarlige Tablets (Mirogabalin), M/s Daiichi Sankyo, Japan
	Detail of previous approval	Numiro 10mg Tablet,Meeting No 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 Approved	
281	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**PERFECT PHARMA (PVT) LTD** 5Km, Manga Road, Raiwind, Lahore **(000469)**
	Application Form Dy. No / Tracking ID & date of submission	(9MM-BAP-MQ1Z, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-09,
	The proposed proprietary name / brand name	**MICRO 5mg Tablet**
	Label Claim	Each film coated tablets contains: Mirogabalin As Besylate 5mg
	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
	Shelf Life (Unit)	2 Year30
	For generic drugs (me-too Status)	Mirogab 5mg Tablet
	Pharmacotherapeutic Group of (API)	Gabapentinoids
	Name, address of Manufacturing site:	Neophar Healthcare Pakistan (Pvt.) Limited-Plot No. 568, Sundar Industrial Estate, Raiwind Road Lahore-
	The status in reference regulatory authorities	Tarlige 5mg Tablets (Mirogabalin), M/s Daiichi Sankyo, Japan
	Detail of previous approval	Numiro 5mg Tablet,Meeting No 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 Approved	
282	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Quaper pvt Ltd** 26-A small industrial estate Lahore road Sargodha **(000609)**
	Application Form Dy. No / Tracking ID & date of submission	(16Y-QB2-6M1B, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**QUTAFIL**
	Label Claim	Each film coated tablet contains: Tdalafil.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature 25 degree centigrade (excursions permitted between 15 to 30 degree centgirade) protect from excessive heat light and moisture.keep out of the reach of children
	For generic drugs (me-too Status)	Cialis tablet 10mg
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction. ATCcode:G04BE08. Tadalafil is a selective, reversible inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5)
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES PVT. LTD.-PLOT NO.313, INDUSTRIAL TRIANGLE, KAHUTA ROAD ISLAMABAD -
	The status in reference regulatory authorities	US FDA APPROVED
	Detail of previous approval	TALDA TABLET 10MG, MEETING No.358
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
283	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Quaper pvt Ltd** 26-A small industrial estate Lahore road Sargodha **(000609)**

	Application Form Dy. No / Tracking ID & date of submission	(17B-2ZB-7WB2, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-24,
	The proposed proprietary name / brand name	**QUTAFIL**
	Label Claim	Each film coated tablet contains: Tadalafil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature 25 degree centigrade (excursions permitted between 15 to 30 degree centgirade) protect from excessive heat light and moisture.keep out of the reach of children
	For generic drugs (me-too Status)	Cialis tablet 20mg
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction. ATCcode:G04BE08. Tadalafil is a selective, reversible inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5)
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES PVT. LTD.-PLOT NO.313, INDUSTRIAL TRIANGLE, KAHUTA ROAD ISLAMABAD -
	The status in reference regulatory authorities	US FDA APPROVED
	Detail of previous approval	TALDA TABLET 20MG, MEETING No.358
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
284	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Quaper pvt Ltd** 26-A small industrial estate Lahore road Sargodha **(000609)**
	Application Form Dy. No / Tracking ID & date of submission	(LAX-BDU-XP53, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-27,
	The proposed proprietary name / brand name	**Quvaren**
	Label Claim	Each film-coated tablet contains: Vardenafil Hydrochloride eq. to Vardenafil.....10mg (Factor1.1852)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature 25 degree centigrade (excursions permitted between 15 to

		30 degree centgirade) protect from excessive heat light and moisture.keep out of the reach of children
	For generic drugs (me-too Status)	Levitra Tablet 10mg
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction, ATC code: G04BE09. Vardenafil is an oral therapy for the improvement of erectile function in men with erectile dysfunction
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES PVT. LTD.-PLOT NO.313, INDUSTRIAL TRIANGLE, KAHUTA ROAD ISLAMABAD -
	The status in reference regulatory authorities	US FDA APPROVED
	Detail of previous approval	VARDA TABLET 10MG, MEETING No.358
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
285	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Quaper pvt Ltd** 26-A small industrial estate Lahore road Sargodha **(000609)**
	Application Form Dy. No / Tracking ID & date of submission	(47U-7X6-PRAL, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-27,
	The proposed proprietary name / brand name	**Quvaren**
	Label Claim	Each film-coated tablet contains: Vardenafil Hydrochloride eq.to Vardenafil.....20mg (Factor1.1852)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature 25 degree centigrade (excursions permitted between 15 to 30 degree centgirade) protect from excessive heat light and moisture.keep out of the reach of children
	For generic drugs (me-too Status)	Levitra Tablet 20mg
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction, ATC code: G04BE09. Vardenafil is an oral therapy for the improvement of erectile function in men with erectile dysfunction
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES PVT. LTD.-PLOT NO.313, INDUSTRIAL TRIANGLE, KAHUTA ROAD ISLAMABAD -
	The status in reference regulatory authorities	US FDA APPROVED

	Detail of previous approval	VARDA TABLET 20MG, MEETING No.358
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
286	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(5SL-5BL-NMMJ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-24,
	The proposed proprietary name / brand name	**GOLIXA (Linzagolix Choline) 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	1x10's, 1x14's, 2x10's, 2x14's, 3x10's-De-Controlled
	Shelf Life (Unit)	2 YearDon't store over 30°C
	For generic drugs (me-too Status)	Lizohil (Linzagolix Choline) 100mg Tablet
	Pharmacotherapeutic Group of (API)	Anti-gonadotropin releasing hormones
	Name, address of Manufacturing site:	M/s. Hilton Pharma (Pvt.) Ltd.-Plot. No. 13-14 & 43, Sector 15, Korangi Industrial Area, Karachi, Pakistan.-
	The status in reference regulatory authorities	Ireland - Yselty 100mg Tablet
	Detail of previous approval	Linzolix , Minutes of 352nd Meeting of Registration Board (19th – 20th November, 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 Approved	
287	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**

	Application Form Dy. No / Tracking ID & date of submission	(71R-JNT-2XJG, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-24,
	The proposed proprietary name / brand name	**GOLIXA (Linzagolix Choline) 200mg Tablet**
	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, 1x14's, 2x10's, 2x14's, 3x10's-De-Controlled
	Shelf Life (Unit)	2 YearDon't store over 30°C
	For generic drugs (me-too Status)	Lizohil (Linzagolix Choline) 200mg Tablet
	Pharmacotherapeutic Group of (API)	Anti-gonadotropin releasing hormones
	Name, address of Manufacturing site:	M/s. Hilton Pharma (Pvt.) Ltd.-Plot. No. 13-14 & 43, Sector 15, Korangi Industrial Area, Karachi, Pakistan.-
	The status in reference regulatory authorities	Ireland - Yselty 200mg Tablet
	Detail of previous approval	Linzolix , Minutes of 352nd Meeting of Registration Board (19th – 20th November, 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 Approved	
288	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hudson Pharma (Pvt) Ltd** D-93, North Western Industrial Zone, Port Qasim Authority **(000842)**
	Application Form Dy. No / Tracking ID & date of submission	(B66-RWP-XLTL, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Tofason**
	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
	Shelf Life (Unit)	2 YearStore in a cool, dry place away from direct light, heat and moisture. Store below 25°C. Keep out of reach of children.
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Immunosuppressants, Janus-associated kinase (JAK) inhibitors; ATC Code: L04AF01
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt) Ltd-Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad,

		Pakistan-
	The status in reference regulatory authorities	MHRA Approved. https://mhraproducts4853.blob.core.windows.net/c
	Detail of previous approval	Medinib 5mg Tablet, Meeting no. 351
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV vide TID 7QH-63V-13HH dated 12 January 2026.	
	Decision	
	Approved Approved	
289	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(R1B-3SY-228X, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-30,
	The proposed proprietary name / brand name	**Setrik 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 YearThis medicine does not require any special storage conditions.
	For generic drugs (me-too Status)	Registered in Pakistan (Arcox Tablet 60 mg)
	Pharmacotherapeutic Group of (API)	M/s Aurore Pharmaceuticals Private Limited.
	Name, address of Manufacturing site:	Aulton Pharmaceuticals.-Plot # 84/1, Block A, Phase 5, Industrial Estate, Hattar, Pakistan-
	The status in reference regulatory authorities	Spain Approved
	Detail of previous approval	Eqaflex 60mg 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 Approved	

290	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(B6D-7LZ-6NPD, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-22,
	The proposed proprietary name / brand name	**Upada ER 15mg Tablet**
	Label Claim	Each Film Coated Extended-Release Tablet contains: Upadacitinib Hemihydrate equivalent to Upadacitinib.....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Upadacitinib is in a class of medications called Janus kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot No.129, Sundar Industrial Estate, Riwind Road, Lahore-
	The status in reference regulatory authorities	Rinvoq (upadacitinib) 15mg Extended-release Tablet of M/s AbbVie Inc.
	Detail of previous approval	Upanib 15mg PR 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 Approved	
291	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Searle IV Solutions (Pvt) Ltd.** 1.5 KM Manga Raiwind Road, Manga Mandi, District Lahore. **(000586)**
	Application Form Dy. No / Tracking ID & date of submission	(RNU-G6A-LYB8, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-10,
	The proposed proprietary name / brand name	**Posazole 100 mg 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, 2x7's, 2x10's, 4x7's, 3x10's,5x10's, 10x10's As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 C
	For generic drugs (me-too Status)	Poshope DR 100MG TAB .Abbott Pharma

	Pharmacotherapeutic Group of (API)	Posaconazole belongs to a class of drugs Azole antifungals that inhibits the enzyme lanosterol 14α-demethylase (CYP51), which catalyses an essential step in ergosterol biosynthesis
	Name, address of Manufacturing site:	Wimits Pharmaceutical Pvt. Limited-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	Posaconazole 100mg DR Tablet by M/S Merck Sharp & Dohme LLC (118446553),(USFDA Approved)
	Detail of previous approval	Minutes of 353rd Meeting of Registration Board (14th – 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	
	Approved Approved	
292	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Macter International Limited** F-216,S.I.T.E.,Karachi-Pakistan **(000141)**
	Application Form Dy. No / Tracking ID & date of submission	(968-Y6B-GUSG, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-01,
	The proposed proprietary name / brand name	**Msanic 1g/5ml Oral Suspension**
	Label Claim	Each 5mL suspension contains: Sucralfate..... 1g (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120ml-De-Controlled
	Shelf Life (Unit)	3 YearStore below 30°C.
	For generic drugs (me-too Status)	Ulsanic 1g/5ml Suspension (Reg. No. 010927) by Highnoon Laboratories
	Pharmacotherapeutic Group of (API)	Drugs for Peptic ulcer and gastro-oesophageal reflux disease (GORD)
	Name, address of Manufacturing site:	Seraph Pharmaceutical - Plot No 210, Industrial Triangle Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	Antepsin 1g/5ml Suspension by Laboratori Baldacci S.p.A., Italy, MHRA Approved
	Detail of previous approval	Sucraph 1g/5ml Oral Suspension approved in 344th meeting of Registration Board (31st December, 2024 – 02nd January, 2025)
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of	

	already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
293	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SKIMS PHARMACEUTICALS** 10/B VALUE ADDITION CITY,KHURRIANWALA **(000830)**
	Application Form Dy. No / Tracking ID & date of submission	(LNJ-WL2-JA6V, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-30,
	The proposed proprietary name / brand name	**Artiva 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 YearStore below 30 degree celsius
	For generic drugs (me-too Status)	Misonate Injection 120mg by Tabros Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antimalarial
	Name, address of Manufacturing site:	Palpex Pharmaceuticals (Pvt.) Ltd-Plot # FD-46-A8, Street-I, Sector 38, Korangi Creek, Industrial Park, Karachi -
	The status in reference regulatory authorities	Artesunate Injection 120mg by Ryvis Pharma (Canada)
	Detail of previous approval	Arkante Injection 120mg, 353rd minutes of meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
294	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	(VWH-2WE-H8R3, 2026-08-20)

	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Silagra 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	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Silda 25mg Tablet Medizan
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 inhibitor PDE5 I
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-PLOT 313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	2EZ-N4V-TJM7
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV vide TID 2EZ-N4V-TJM7 dated 30 January 2026..	
	Decision	
	Approved Approved	
295	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	(WNM-QSY-4NPU, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Silagra 50mg Tablet**
	Label Claim	Each filmcoated tablet contains: Sildenafil Citrate eq. to Sildenafil 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Silda 50mg Tablet Medizan
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 inhibitor PDE5 I
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	DV9-RME-6JB8
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant	

	application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV.	
	Decision	
	Approved Approved	
296	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	(TU1-SY4-1JMV, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-02,
	The proposed proprietary name / brand name	**Silagra 100mg Tablet**
	Label Claim	Each filmcoated tablet contains: Sildenafil Citrate eq. to Sildenafil 100mg
	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)	Silda 100mg Tablet Medizan
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 5 inhibitor PDE5 I
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	882-QQY-J4Y2
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV.	
	Decision	
	Approved Approved	
297	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(JX9-NW6-WZ3T, 2026-08-20)

	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Avapag Tablet 20mg**
	Label Claim	Each Film Coated Tablet contains: Avatrombopag Maleate 23.6mg Eq. to Avatrombopag..... 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 C
	For generic drugs (me-too Status)	Ambopag Tablet 20mg
	Pharmacotherapeutic Group of (API)	Thrombopoietin Receptor Agonist
	Name, address of Manufacturing site:	Platinum Pharmaceuticals (Pvt) Ltd.,-Plot no. A-20, North Western Industrial Zone, Bin Qasim Authority, Karachi-75020, Pakistan.-
	The status in reference regulatory authorities	Food and Drug Administration
	Detail of previous approval	345 RB Meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
298	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT **(000941)**
	Application Form Dy. No / Tracking ID & date of submission	(ZPX-BDG-VXMM, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-23,
	The proposed proprietary name / brand name	**SEFOBAC INJECTION**
	Label Claim	Each Vial Contains: Cefoperazone (as sodium).....1g Sulbactum (as sodium).....1g
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Perabactum by Martin Dow
	Pharmacotherapeutic Group of (API)	Cefoperazone: Third-generation cephalosporin. Sulbactam: Beta-lactamase Inhibitors
	Name, address of Manufacturing site:	M/s Biogen Life Sciences -8Km, Chakbeli Road Rawat, Rawalpindi -
	The status in reference regulatory authorities	PMDA Japan Approved
	Detail of previous approval	(M-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 Approved	
299	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	(59R-Y1Y-NZVX, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-05,
	The proposed proprietary name / brand name	**Merome 80mg Tablet**
	Label Claim	Each film coated tablet contains: Resmetirom 80mg
	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)	REZDIFFRA 80mg Tablet
	Pharmacotherapeutic Group of (API)	Selective thyroid hormone receptor modulators THRMs.
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Product approved in 350th meeting contract manufacturing and product shift self manufacturing against PRVC meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV .	
	Decision	
	Approved Approved	
300	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	(5SG-Q31-DHPG, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-09,
	The proposed proprietary name / brand name	**Maclol 0.5mcg Soft Gel Capsule**
	Label Claim	Each soft gelatin capsule contains: Calcitriol .....0.5mcg (BP Spec)
	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)	generic product
	Pharmacotherapeutic Group of (API)	Vitamin-D Analogue
	Name, address of Manufacturing site:	Biogen Life Sciences -8-km Chakbeli Road Rawat-Rawalpindi -
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	336th MInutes of meeting helad on 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 Approved	
301	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	(QLR-4GE-9JYY, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-30,
	The proposed proprietary name / brand name	**Dalafi**
	Label Claim	Each film coated tablet contains: Tadalafil .....20 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x1's, 1x5's, 1x7's, 1x10's, 2x7's, 2x10's, 3x7's 4x7's, 3x10's-As per SRO
	Shelf Life (Unit)	24 Monthless than 30 C
	For generic drugs (me-too Status)	Dalafi 20 mg tablet by Linta Pharmaceuticals
	Pharmacotherapeutic Group of (API)	M/s Rakshit Pharmaceuticals private Limited
	Name, address of Manufacturing site:	Linta Pharmaceuticals Private Limited-Linta Pharmaceuticals (Pvt) Ltd Plot # 3,Street # S-5 National Industrial Zone Rawat Islamabad -

	The status in reference regulatory authorities	Viagra of fizer RRA Status: Cialis of LILLY ICOS LLC by Eli Lilly of USA, Approved in FDA
	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 Approved	
302	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	(J1P-SJG-5D12, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-30,
	The proposed proprietary name / brand name	**Aronix 50 mg**
	Label Claim	50 mg per Tablet
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 2x4's, 3x4's, 3x4's-As per SRO
	Shelf Life (Unit)	24 Monthless than 30 C
	For generic drugs (me-too Status)	manufacture by Linta Pharma
	Pharmacotherapeutic Group of (API)	M/s Rakshit Pharmaceutical Pvt Ltd, India
	Name, address of Manufacturing site:	Linta Pharmaceuticals Private Limited -Linta Pharmaceuticals (Pvt) Ltd Plot # 3,Street # S-5 National Industrial Zone Rawat Islamabad -
	The status in reference regulatory authorities	Approved in FDA
	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 Approved	
303	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	(615-SUH-SP3J, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-30,
	The proposed proprietary name / brand name	**Aronix 100 mg**
	Label Claim	each Tablet contain 100 mg of sildinafil Citrate
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 2x4's, 3x4's, 3x4's-As per SRO
	Shelf Life (Unit)	24 Monthless than 30 C
	For generic drugs (me-too Status)	Aronix 100 mg by Linta Pharmaceuticals Pvt.Ltd
	Pharmacotherapeutic Group of (API)	M/s Rakshit Pharmaceutical
	Name, address of Manufacturing site:	Linta Pharmaceuticals-Linta Pharmaceuticals (Pvt) Ltd Plot # 3,Street # S-5 National Industrial Zone Rawat Islamabad -
	The status in reference regulatory authorities	Approved in FDA
	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 Approved	
304	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well & Well Pharma Pvt.Ltd** Plot No 07, Street S-8, RCCI, Rawat Rawalpindi **(000687)**
	Application Form Dy. No / Tracking ID & date of submission	(LQ5-UER-M4PA, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-28,
	The proposed proprietary name / brand name	**Culis 20mg**
	Label Claim	Each film-coated tablet contains: Tadalafil..... 20mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x2's; 1x4's; 2x4's; 1x10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30%
	For generic drugs (me-too Status)	Taldex 20mg Tab Reg No 135751 MS Jinnah Pharma
	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	SRA Registration Status: US FDA Approved

	Detail of previous approval	Dalafil 20mg Tablet Reg No 132631 in DRB Meeting 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 Approved	
305	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	(VAJ-EWH-TRAZ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-31,
	The proposed proprietary name / brand name	**LAKZOL 1% Cream**
	Label Claim	Each gm Cream Contains: Luliconazole..... 10 mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year20-25°C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Anti Fungal agent for topical use
	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	Lunaz 1% Cream / Minutes of 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 Approved	
306	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	(XW8-D3J-AV66, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-31,
	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 Year20-25°C
	For generic drugs (me-too Status)	Omaril Tablet / Genix Pharma
	Pharmacotherapeutic Group of (API)	DPP-4 inhibitor
	Name, address of Manufacturing site:	M/s Wnsfeild Pharmaceuticals-Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Omergo 12.5mg Tablet / Minutes of 353rd 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 Approved	
307	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	(EQA-7L8-2QMS, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-31,
	The proposed proprietary name / brand name	**OMERGO 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-As per SRO
	Shelf Life (Unit)	2 Year20-25°C
	For generic drugs (me-too Status)	Omaril Tablet / Genix Pharma
	Pharmacotherapeutic Group of (API)	DPP-4 inhibitor
	Name, address of Manufacturing site:	M/s Wnsfeild Pharmaceuticals-Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.-

	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Omergo 25mg Tablet / Minutes of 352nd 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 Approved	
308	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	(S57-TTG-6PV9, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-31,
	The proposed proprietary name / brand name	**Savel 800mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Sevelamer Carbonate..... 800mg (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)	NeoVel Seraph Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anti-hyper phosphatemia (Treatment of hyperkalaemia and hyperphosphataemia
	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	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Savelo 800mg Tablet Minutes for 340th 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 Approved	

309	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	(Z11-U4H-YNXV, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-22,
	The proposed proprietary name / brand name	**Itowin Capsule 100mg**
	Label Claim	Each Capsule contains: Immediate Release Pellets of Itraconazole eq. to Itraconazole.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Zacon Capsule of M/s Wimits Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antifungal Agents
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Itraconazole Heumann 100 mg hard capsules of M/s HEUMANN PHARMA GmbH & Co. Generica KG (Federal Institute for Drugs and Medical Devices Approved)
	Detail of previous approval	Itracon 100mg Capsule approved in 350th 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 Approved	
310	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	(1LD-YJD-M1JD, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-22,
	The proposed proprietary name / brand name	**Flucowin Topical Oil**
	Label Claim	Each gram of scalp oil contains: Fluocinolone acetonide.....0.11mg (0.01%)
	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)	Derma smooth By M/S Valor Pharma
	Pharmacotherapeutic Group of (API)	Topical Steroid
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd-Plot No. 17, Special Industrial Zone (EPZ), Risalpur-
	The status in reference regulatory authorities	Derma-Smoothe/FS By Hill Dermaceuticals, Inc. Sanford, Florida 32773
	Detail of previous approval	Derma Cal Topical Oil approved in 347th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
311	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	(XUT-G5H-T831, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-22,
	The proposed proprietary name / brand name	**Minowin 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 Centi Grade
	For generic drugs (me-too Status)	Hair Max 5% w/v Topical Solution by ELko Organization
	Pharmacotherapeutic Group of (API)	Vasodilator
	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	BOSLEY MAN 5% TOPICAL SOLUTION USFDA APPROVED
	Detail of previous approval	Regain 5% Topical Solution 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 Approved	
312	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**wise pharmaceuticals** Plot No 3-A, Street No S-1 RCCI Industrial Estate Rawat. Rawalpindi **(000625)**
	Application Form Dy. No / Tracking ID & date of submission	(3B3-NBY-YPLG, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-02-26,
	The proposed proprietary name / brand name	**DEXOWIN 60MG CAPSULE**
	Label Claim	Each hard gelatin Capsule contains: DDR Pellets of Dexlansoprazole Eq. to Dexlansoprazole..... 60mg (Product Specs: Innovator)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Dexxoo 60mg Capsule
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI) WHO ATC Code: A02BC06
	Name, address of Manufacturing site:	M/s Swera Pharmaceuticals-PLOT 27 STREET S4, NATIONAL INDUSTRIAL ZONE, RAWAT INDUSTRIAL ESTATE RAWAT-
	The status in reference regulatory authorities	DEXILANT delayed-release capsules (DEXILANT capsules) Country where sold / registered; USA Manufactured by: Takeda Pharmaceuticals U.S.A
	Detail of previous approval	M-320 (115251)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
313	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**wise pharmaceuticals** Plot No 3-A, Street No S-1 RCCI Industrial Estate Rawat. Rawalpindi **(000625)**
	Application Form Dy. No / Tracking ID & date of submission	(HDJ-4XU-YDHD, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-02-26,
	The proposed proprietary name / brand name	**REZAL 40MG INJECTION**

	Label Claim	Each vial contains: Omeprazole sodium equ. to Omeprazole 40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Ruling 40mg Injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI) WHO ATC Code: A02BC01
	Name, address of Manufacturing site:	M/s Swera Pharmaceuticals-PLOT 27 STREET S4, NATIONAL INDUSTRIAL ZONE, RAWAT INDUSTRIAL ESTATE RAWAT-
	The status in reference regulatory authorities	Omeprazole 40mg powder for solution for infusion Country where sold / registered; UK Manufactured by: SANDOZ Park view, Riverside way, Watchmoor aprk, Camerley, Surrey GU153YL UK www.sandoz.com
	Detail of previous approval	M-322 (115473)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
314	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**
	Application Form Dy. No / Tracking ID & date of submission	(YDJ-79D-LJTJ, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-05,
	The proposed proprietary name / brand name	**Vonara 10mg Tablet**
	Label Claim	Each film-coated tablet contains: Vonoprazan Fumarate equivalent to Vonoprazan ... 10 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Vocinti Tablet 10mg
	Pharmacotherapeutic Group of (API)	Zhejiang Hengkang Pharmaceutical Co., Ltd
	Name, address of Manufacturing site:	M/s. Swiss Pharmaceuticals-Plot: A/159,S.I.T.E,Super Highway, Karachi-
	The status in reference regulatory authorities	Vocinti 10mg.
	Detail of previous approval	Vonokat 10mg Tablet.124612
	Evaluation Remarks	

	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV.	
	Decision	
	Approved Approved	
315	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maple Pharmaceuticals (Pvt.) Ltd.** Plot No.147, Sector 23, Korangi Industrial Area, Karachi-74900, Pakistan **(000620)**
	Application Form Dy. No / Tracking ID & date of submission	(HZ1-BTW-PMGD, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-05,
	The proposed proprietary name / brand name	**Vonara 20mg Tablet**
	Label Claim	Each film-coated tablet contains: Vonoprazan Fumarate equivalent to Vonoprazan ... 20 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Vocinti Tablet 20mg
	Pharmacotherapeutic Group of (API)	Zhejiang Hengkang Pharmaceutical Co., Ltd
	Name, address of Manufacturing site:	M/s. Swiss Pharmaceuticals-Plot: A/159,S.I.T.E,Super Highway, Karachi-
	The status in reference regulatory authorities	Vocinti 20mg.
	Detail of previous approval	Vonokat 20mg Tablet,124613
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV.	
	Decision	
	Approved Approved	
316	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	(2SS-4LP-GHZH, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-10,
	The proposed proprietary name / brand name	**Xanoline 50mg/20mg Tablet**
	Label Claim	Each capsule contains: Xanomeline as Tartrate eq. to Xanomeline Pellets 19.4% 50mg Trospium Chloride Pellets 18.6% 20mg
	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)	COBENFY capsule coated pellets
	Pharmacotherapeutic Group of (API)	Muscarinic agonists
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	359TH meeting approved
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
317	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	(11N-UZQ-T5ZG, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-10,
	The proposed proprietary name / brand name	**Xanoline 100mg/20mg Capsule**
	Label Claim	Each capsule contains: Xanomeline as Tartrate eq. to Xanomeline Pellets 19.4% 100mg Trospium Chloride Pellets 18.6% 20mg
	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)	COBENFY capsule coated pellets
	Pharmacotherapeutic Group of (API)	Muscarinic agonists
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	359TH meeting approved

	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
318	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	(JNA-M4D-GH27, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-10,
	The proposed proprietary name / brand name	**Xanoline 125mg/30mg Capsule**
	Label Claim	Each capsule contains: Xanomeline as Tartrate eq. to Xanomeline Pellets 19.4% 125mg Trospium Chloride Pellets 18.6% 30mg
	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)	COBENFY capsule coated pellets
	Pharmacotherapeutic Group of (API)	Muscarinic agonists
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	359TH meeting approved
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
319	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Epoch pharma** Plot No 83-85 Sector 15 korangi Industrial Area **(000425)**

	Application Form Dy. No / Tracking ID & date of submission	(696-W41-Y3X5, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**Encef Injection 500mg**
	Label Claim	Each vial contains: Cefepime (as HCl) with L-Arginine .....500mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Maxum Injection Registration Number: 006059 by Highnoon
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE Super Highway, Phase-II, Karachi-
	The status in reference regulatory authorities	Maxim Injection FDA Approved Manufactured by: Orchid Healthcare (A Division of Orchid Chemicals & Pharmaceuticals Ltd.)
	Detail of previous approval	Megapime 1gm Injection Registration Number 058178 approved in PRVC for Elko Pharmaceuticals Letter is attached for reference
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV	
	Decision	
	Approved Approved	
320	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Epoch pharma** Plot No 83-85 Sector 15 korangi Industrial Area **(000425)**
	Application Form Dy. No / Tracking ID & date of submission	(62G-WWU-D2UT, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**Osit Injection 8mg**
	Label Claim	Each 4ml contains: Ondansetron Hydrochloride Dihydrate eq. to Ondansetron .....8mg (Product Specs: USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's, 5's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Onset 8mg/4ml Injection by M/s Pharmedic (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Antiemetic

	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE Super Highway, Phase-II, Karachi-
	The status in reference regulatory authorities	Zofran 8mg /4ml injection By Novartis Pharmaceuticals Approved by Health Canada
	Detail of previous approval	ONFRAN INJ. 8mg/4ml 059282 Dated 15th April 2026
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV	
	Decision	
	Approved Approved	
321	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	(ZUZ-97V-UTUD, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-22,
	The proposed proprietary name / brand name	**Ferric Maltol**
	Label Claim	Each capsule contains: Iron as Ferric Maltol .....30mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's 30's-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	Ferric Maltol 20mg Capsule by AGP Pharma
	Pharmacotherapeutic Group of (API)	Anti enemic
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-Plot # 313, Industrial Triangle, Kahuta road, Islamabad, Pakistan -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	352 DRAP Meeting
	Evaluation Remarks	
	The firm has given cross-reference of a product approved in the PRVC vide TID 56G-8WZ-XRG1 dated 31-March, 2026. 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	

	Approved	
322	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	(UP9-X7Z-SLXG, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-07-15,
	The proposed proprietary name / brand name	**Dexla 60mg Capsules**
	Label Claim	Each 60mg Capsule contains: Dexlansoprazole (enteric coated pellets) eq. to dexlansoprazole.....60mg (Product complies innovator specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3x10's -As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	Dextop 60mg Searl Pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Name, address of Manufacturing site:	Gulf Pharmaceuticals-Plot# 49, Street # S−5, Rawalpindi Industrial zone, Islamabad-Pakistan-
	The status in reference regulatory authorities	FDA
	Detail of previous approval	357 DRAP 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 Approved	
323	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(TPG-W6B-34JX, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-04-29,
	The proposed proprietary name / brand name	**Biltin 10mg Tablet**
	Label Claim	Each Orodispersible Tablet contains: Bilastine .....10MG (Product Complies Innovators Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c

	For generic drugs (me-too Status)	Bilix 10 mg by AGP Pharma
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, Industrial Estate, Rawat-
	The status in reference regulatory authorities	UK Mhra Approved
	Detail of previous approval	Biltex, DRB 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 Approved	
324	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(4W4-GVM-MUB7, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-25,
	The proposed proprietary name / brand name	**FWH 2% + 1% Cream**
	Label Claim	Each gm Contains: Fusidic acid (BP).....20mg (2% w/w) Hydrocortisone Acetate (USP).....10mg (1%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 Yearbelow 25c
	For generic drugs (me-too Status)	Fosic-H Cream by Metro Pharmaceuticals
	Pharmacotherapeutic Group of (API)	angiotensin II receptor antagonists./ diuretics
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Block B, Phase-I&II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	UK MHRA
	Detail of previous approval	FWH 2% + 1% CREAM, 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	

	Approved	
325	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(3GX-TV1-WS9W, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**CEFWIS 500mg INJECTION**
	Label Claim	Each vial contains; Cefepime HCl Monohydrate eq. to Cefepime.....500mg (With L-Arginine) (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 25c
	For generic drugs (me-too Status)	OPIME 500mg INJECTION by IMCO PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Block B, Industrial Estate, Hattar-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Accupine 500mg Injection, 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
326	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(69V-4QT-5YG2, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**Cefopara 1gm Injection**
	Label Claim	Each vial contains; Cefoperazone as sodium.....500mg Sulbactum as sodium.....500mg (Product Complied JP Specs)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As per SRO-As per SRO

	Shelf Life (Unit)	2 YearStore Below 25c
	For generic drugs (me-too Status)	Uszone Injection by Usawa Pharma
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar-
	The status in reference regulatory authorities	PMDA Japan
	Detail of previous approval	Prazon Injection, DRB 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
327	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(4AX-G4Z-W6L5, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**Mexton Eye Drops**
	Label Claim	Each ml Contains: Moxifloxacin Hydrochloride as moxifloxacin ...5mg(0.5%) (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25c
	For generic drugs (me-too Status)	Azlox Opthalmic Solution Alza Pharmaceuticals 081625
	Pharmacotherapeutic Group of (API)	FLoroquinolone Antibiotics
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot no. 69/1, Block-B, Phase I-II, Industrial Estate, Hattar-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Monexi, DRB 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved Approved	
328	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(GUR-Y8U-1EBV, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**CEFWIS 1000mg INJECTION**
	Label Claim	Each vial contains; Cefepime HCl Monohydrate eq. to Cefepime.....1000mg (With L-Arginine) (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 25c
	For generic drugs (me-too Status)	OPIME 1000mg INJECTION by IMCO PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Block B, Industrial Estate, Hattar-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Accupine 1g Injection, 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
329	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(GXU-DTP-ZBN5, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**SYLBO 200mcg DPI Capsule**
	Label Claim	Each Rotacapsule contains: Salbutamol as Sulphate.....200mcg (Product Complies BP Specs)
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25c
	For generic drugs (me-too Status)	Aerotec 200mcg Capsule Highnoon Laboratories (Reg# 044593)
	Pharmacotherapeutic Group of (API)	bronchodilators
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot no. 69/1, Block-B, Phase I-II, Industrial Estate, Hattar-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	SBT, DRB 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
330	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(PVR-TSP-A9UE, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-25,
	The proposed proprietary name / brand name	**Fodic 2% Cream**
	Label Claim	Each gm Contains: Fusidic acid (BP).....20mg (2% w/w) (Product complies BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 25c
	For generic drugs (me-too Status)	Ucid 2% Cream by Ciba Pharmaceuticals
	Pharmacotherapeutic Group of (API)	angiotensin II receptor antagonists./ diuretics
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar-
	The status in reference regulatory authorities	UK MHRA
	Detail of previous approval	Fosid 2% Cream, 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 Approved	
331	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)**
	Application Form Dy. No / Tracking ID & date of submission	(Q7E-RGE-69AU, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-06-27,
	The proposed proprietary name / brand name	**CEFWIS 2000mg INJECTION**
	Label Claim	Each vial contains; Cefepime HCl Monohydrate eq. to Cefepime.....2000mg (With L-Arginine) (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 25c
	For generic drugs (me-too Status)	Fexnit 2g Injection by Fexnit 2g Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Block B, Industrial Estate, Hattar-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Accupine 2g Injection, 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
332	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(SJA-LU8-XGDP, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Dydrone 10mg Tablet**
	Label Claim	Each film coated tablet contains 10 mg of Dydrogesterone.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-As per SRO

	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Dydrogest 10mg Tablet of M/s OBS Pakistan Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Genito Urinary system and sex hormones.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals Pvt. Ltd.-Plot # 01, AL Badar Idustrial Estate Phase II, Sheikhupura Road, Sheikhupura Sheikhupura-
	The status in reference regulatory authorities	Duphaston 10 mg film-coated tablets of M/s Mylan IRE Healthcare Limited, Duphaston 10 mg film-coated tablets ® is Approved in HPRA of Ireland.
	Detail of previous approval	D-Gest 10mg Tablet - 336th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
333	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(SPX-1Q9-NARW, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-03-03,
	The proposed proprietary name / brand name	**HYDROSONE 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 YearStore below 25°c
	For generic drugs (me-too Status)	CORTISONE 100MG INJECTION by VISION PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-Plot No. 31 & 32, Punjab Small Industrial Estate, Taxila, Rawalpindi-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Hykor 100mg Injection, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product	

	formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
334	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(8D4-QNT-PNP5, 2026-08-20)
	Detail of Fee Submitted	97200, 2026-03-03,
	The proposed proprietary name / brand name	**HYDROSONE 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 YearStore below 25°c
	For generic drugs (me-too Status)	CORTISONE INJECTION by VISION PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-Plot No. 31 & 32, Punjab Small Industrial Estate, Taxila, Rawalpindi-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	Hykor 250mg Injection, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
335	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**Bloom Pharmaceuticals (Pvt) Ltd.** Plot No. 30, Phase I & II, Industrial Estate, Hattar **(000374)**
	Application Form Dy. No / Tracking ID & date of submission	(XT4-HTE-X17L, 2025-06-05)
	Detail of Fee Submitted	37000.0, 2025-04-15,
	The proposed proprietary name / brand name	**Blotap Tablet 50mg**

	Label Claim	Each film coated tablet contains: Tapentadol Hydrochloride eq. to Tapentadol.....50mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO (10s, 20s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a cool and dry place.
	For generic drugs (me-too Status)	Tapento Tablet 50mg by M/s Sami Pharmaceuticals (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Opioid Analgesics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batch No. T-01, Batch No. T-02 and Batch No. T-03.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice, Packing List, COA, Form 3, Form 7 and Form 6 are attached in dossier
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Studies done between Blotap 50mg Tablet and Tapento 50mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in the dossier for Batch No. TPD01190001/U-1, TPD01190002/U-1 and TPD01190003/U-1
	The status in reference regulatory authorities	NYUCYNTA 50mg Tablets (USFDA Approved)
	GMP status of the firm	Valid for 3 years. Last inspection was conducted on 14-07-2024 and 03-09-2024
	Evidence of approval of manufacturing facility	Valid Tablet (General) Section Approval Letter dated 15-09-2021, is attached in dossier
	Evaluation Remarks	
	The applicant has stated that “the HPLC system is not 21 CFR Part 11 compliant.”	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
336	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**Bloom Pharmaceuticals (Pvt) Ltd.** Plot No. 30, Phase I & II, Industrial Estate, Hattar **(000374)**
	Application Form Dy. No / Tracking ID & date of submission	(TM6-P74-Y7LA, 2025-06-05)
	Detail of Fee Submitted	37000.0, 2025-04-15,
	The proposed proprietary name / brand name	**Blotap Tablet 75mg**
	Label Claim	Each film coated tablet contains: Tapentadol Hydrochloride eq. to Tapentadol.....75mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO (10s, 20s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a cool and dry place.
	For generic drugs (me-too Status)	Tapento Tablet 75mg by M/s Sami Pharmaceuticals (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Opioid Analgesics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	

	Detail of stability batches of drug product	Batch No. T-01, Batch No. T-02 and Batch No. T-03.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice, Packing List, COA, Form 3, Form 7 and Form 6 are attached in dossier
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Studies done between Blotap 75mg Tablet and Tapento 75mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in the dossier for Batch No. TPD01190001/U-1, TPD01190002/U-1 and TPD01190003/U-1
	The status in reference regulatory authorities	NYUCYNTA 75mg Tablets (USFDA Approved)
	GMP status of the firm	Valid for 3 years. Last inspection was conducted on 14-07-2024 and 03-09-2024
	Evidence of approval of manufacturing facility	Valid Tablet (General) Section Approval Letter dated 15-09-2021, is attached in dossier
	Evaluation Remarks	
	The applicant has stated that “the HPLC system is not 21 CFR Part 11 compliant.”	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
337	Case Category	Routine (Iqra Aftab)
	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	(91B-8BT-V6UH, 2025-04-06)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-30, 2024-10-10
	The proposed proprietary name / brand name	**TAPENDA IR Tablets 75mg**
	Label Claim	Each film coated tablet contains: Tapentadol HCl eq. to Tapentadol 75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's,10's,14's,20's,2-De-Controlled
	Shelf Life (Unit)	24 MonthStore below 30C
	For generic drugs (me-too Status)	Available ; Tapento IR Tablets by SAMI Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Ami Lifesciences Private Limited (ALPL)
	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	Nucynta® Tablets 75mg approved by USFDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	The chromatograms of dissolution testing are same with altered injection date and area.	
	Decision	
	Rejected Registration Board decided to reject the instant application, considering that the firm had submitted the exact same chromatograms for different samples of comparative dissolution testing with altered injection date and area only.	
338	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**Bloom Pharmaceuticals (Pvt) Ltd.** Plot No. 30, Phase I & II, Industrial Estate, Hattar **(000374)**
	Application Form Dy. No / Tracking ID & date of submission	(4RQ-U9B-5647, 2025-04-07)
	Detail of Fee Submitted	37000.0, 2025-02-06,
	The proposed proprietary name / brand name	**Blonam 2mg Tablets**
	Label Claim	Each tablet contains: Clonazepam.....2mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO (1x10s, 3-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature, in a cool and dry place. Protect from heat and light.
	For generic drugs (me-too Status)	Rivotril Tablets 2mg by Roche Pakistan Limited
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Klonopin Tablets by Roche (USFDA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The data given in the dossier is for the batches manufactured in 2022 and at that time our company was not having CFR. Compliant HPLC software. That's why we could not provide compliance data and audit trail reports for old hatches.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
339	Case Category	Routine (Iqra Aftab)
	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	(9G7-XQ1-7MYW, 2025-02-07)

	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**EBCAL SYRUP**
	Label Claim	Each 5ml contains: Ebastine 5mg
	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)	Kestine Syrup By M/s High Noon Laboratories
	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	EBASTEL 1 MG/ML SOLUCIÓN ORAL By Almirall, S.A.General Mitre, 15108022 Barcelona
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Currently the system is not 21 CFR Compliant.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
340	Case Category	Contract Manufacturing (Iqra Aftab)
	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	(82L-PHR-J97M, 2025-03-17)
	Detail of Fee Submitted	93000.0, 2024-11-21,
	The proposed proprietary name / brand name	**LacoZen 50mg Tablet**
	Label Claim	Each film coated tablet contains: Lacosamide.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Vimpex 50mg Tablet by Genome P h a r m a c e u t i c a l s (077447)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Swiss Pharmaceuticals Pvt. Ltd.-A-159, S.I.T.E. Super Highway, Karachi-Pakistan-

	Name & address of API manufacturer	M/s. RAGHAVA LIFE SCIENCES PVT LTD. SY. NO.888 & 901,JANGAMPALLY VILLAGE, BHIKNOOR MANDAL, KAMAREDDY DIST,TELANGANA503101 INDIA DUNS number: 85-554-4030
	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	Vimpat 50 mg film-coated tablets by UCB Pharma Limited, EMA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The applicant has stated that the system is not 21 CFR Part 11 compliant and the audit trail functionality has not been activated.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
341	Case Category	Routine (Iqra Aftab)
	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	(225-7RB-BNNM, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2024-12-09,
	The proposed proprietary name / brand name	**LacoZen 10mg/ml Injection**
	Label Claim	Each 20ml vial contains: Lacosamide.....200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Lacozen Injection by Swiss Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Swiss Pharmaceuticals Pvt. Ltd.-A-159, S.I.T.E. Super Highway, Karachi-Pakistan-
	Name & address of API manufacturer	M/s. RAGHAVA LIFE SCIENCES PVT LTD. SY. NO.888 & 901,JANGAMPALLY VILLAGE, BHIKNOOR MANDAL, KAMAREDDY DIST,TELANGANA503101 INDIA DUNS number: 85-554-4030
	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	Vimpat 10mg/ml Injection by UCB Pharma Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, UK EMA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The applicant has stated that the system is not 21 CFR Part 11 compliant and the audit trail functionality has not been activated.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
342	Case Category	Routine (Iqra Aftab)
	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	(DM9-X31-DXR6, 2025-02-07)
	Detail of Fee Submitted	37000.0, 2024-11-21,
	The proposed proprietary name / brand name	**Lacomed 10mg/ml Oral Solution**
	Label Claim	Each ml of Oral Solution contains: Lacosamide.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Lacolep 10mg/ml Oral solution by Hilton Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. RAGHAVA LIFE SCIENCES PVT LTD. SY. NO.888 & 901,JANGAMPALLY VILLAGE, BHIKNOOR MANDAL, KAMAREDDY DIST,TELANGANA503101 INDIA DUNS number: 85-554-4030
	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	VIMPAT (lacosamide) Oral Solution by UCB, Inc. Smyrna, GA 30080, USA FDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	The applicant has stated that the HPLC system is not 21 CFR compliant.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
343	Case Category	Routine (Iqra Aftab)
	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	(L7V-ES8-QXPD, 2025-05-09)
	Detail of Fee Submitted	37000.0, 2025-03-13,
	The proposed proprietary name / brand name	**Levocit 2.5mg/5ml Syrup**
	Label Claim	Each 5ml of syrup contains: Levocetirizine Dihydrochloride.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml, 60ml, 120ml-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Brand Name: T-Day 2.5mg/5ml Oral solution (60ml), Registration holder: M/s Novartis Pharma Pak Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. HEMA PHARMACEUTICALS PVT. LTD. Address: Plot No. 6201/A&B, Opp. Ewac Alloys Ltd., GIDC Estate, Ankleshwar – 393002 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	Brand Name: Xyzal 0.5 mg/ml oral solution, Manufacturer: Aesica Pharmaceuticals S.r.l., Via Praglia 15, l-10044, Pianezza (TO), Italy. Marketing Authorization holder: LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The applicant has stated that the HPLC system is not 21 CFR compliant.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	

344	Case Category	Contract Manufacturing (Najia Saleem)
	Name, address of Applicant.	**Surge Laboratories (Pvt.) Ltd.** 10th KM, Faisalabad Road, Bikhi District, Sheikhupura. **(000484)**
	Application Form Dy. No / Tracking ID & date of submission	(MTQ-GS8-EYGZ, 2025-06-05)
	Detail of Fee Submitted	93000.0, 2025-03-18,
	The proposed proprietary name / brand name	**SURFALIN**
	Label Claim	Each film coated tablet contains: Lefamulin (as Lefamulin acetate) .....600mg (Innovator's Specification)
	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)	2 YearStore below 30 degree celsius
	For generic drugs (me-too Status)	LEFALY TABLET 600MG , HORIZON PHARMACEUTICAL PAKISTAN
	Pharmacotherapeutic Group of (API)	Pleuromutilin antiobiotic
	Name, address of Manufacturing site:	Nabiqasim industries-17/24, korangi industrial area, karachi, Karachi- Pakistan-
	The status in reference regulatory authorities	FDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected "No" but later on replied in response to a query that their contract manufacturing product has been approved in 352nd meeting of the Registration Board and submitted undertaking, module I, extract of minutes. The firm shall submit fee Rs. 9400/- before issuance of registration letter.	
	Decision	
	Approved The firm shall submit fee Rs. 9400/- as applicable on cross-referred cases, before issuance of registration letter.	
345	Case Category	Contract Manufacturing (Najia Saleem)
	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	(WWV-57P-DMQQ, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-01-10,
	The proposed proprietary name / brand name	**Finen 20mg Tablet**
	Label Claim	Each film coated tablet contain: Finerenone ..... 20mg Innovator's Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-De-Controlled,2x10's-De-Controlled,3x10's-De-Controlled,4x7's-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 30oC
	For generic drugs (me-too Status)	None
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt). Ltd-Plot No.129' Sunder Industrial Estate Raiwind Road Lahore-

	Name & address of API manufacturer	NA
	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	KERENDIA 20mg TABLET Bayer Healthcare Pharmaceutical Inc UFSDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has stated that "we have applied TAFIN 10mg TABLET (Finerenone) Tracking ID EEV-Y544GJ9 and TAFIN 20mg TABLET (Finerenone) Tracking ID T41-R2M-3DL8 for which we are intend to continue our products for registration. However, we also applied the same molecule on contract manufacturing basis with WIMITS Pharmaceuticals FINEN 10mg TABLET Tracking ID ZB1-Y55-BJUJ and FINEN 20mg TABLET Tracking ID WWV-57P-DMQQ for which we are not interested to continue these applications."	
	Decision	
	Rejected The Board acceded the request of the firm and rejected the case.	
346	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**Biogen Life Sciences** 8-KM, Chak Beli Road, Rawat, **(000911)**
	Application Form Dy. No / Tracking ID & date of submission	(MA2-TEH-5796, 2024-10-29)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	**Bi-Set 8mg Injection**
	Label Claim	Each 4ml contains: Ondansetron as HCl 8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's & 5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Condition
	For generic drugs (me-too Status)	Manufacturer Name Pharmedic Laboratories Brand Name Onset Injection
	Pharmacotherapeutic Group of (API)	5HT3 receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sonia Organics
	Detail of stability batches of drug product	3 batches of 2000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Ms Bio Mark without timely intimation to DRAP; hence, may be verified accordingly
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE against Onset injection of Ms Pharmedic
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	as per zone-IV A conditions
	The status in reference regulatory authorities	ZOFRAN 8mg Injection
	GMP status of the firm	
	Evidence of approval of manufacturing facility	submitted

	Evaluation Remarks	
	The firm has borrowed API from Ms Bio Mark without timely intimation to DRAP; hence, may be verified accordingly. Moreover, the firm has submitted GMP certificate of API valid at the time of submission but is expired now, hence, valid GMP certificate shall be submitted before issuance of registration letter.	
	Decision	
	Approved The firm shall submit the following before issuance of registration letter: i. copies of valid GMP and DML of the applicant ii. API loan verification.	
347	Case Category	Routine (Najia Saleem)
	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	(DUV-HVD-ZRUX, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-11-14,
	The proposed proprietary name / brand name	**BARICIT 2MG TABLETS**
	Label Claim	Each film coated tablet contains: Baricitinib.....2mg (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 Year(s)Below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	JAK inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	ANHUI HAIKANG PHARMACETICAL CO., LTD , NO.21 HUANCHENG WEST ROAD, ANQING CITY, ANHUI PROVINCE,
	Detail of stability batches of drug product	Three batches of 1500 tablets each (24HT16, 24HT17 and 24HT18)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted clearance certificate
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP against Barinib 2mg tablet of Ms General pharmaceuticals, Bangladesh
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	Olumiant 2mg tablets (USFDA Approved)
	GMP status of the firm	New DML granted on 17-01-2024
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Deferred in M-360 for submission of both accelerated and real time stability data of 6th month time point for batch 24HT18 since 6th month stability data for only two batches has been submitted. Updated status: Submitted the required data	
	Decision	
	Approved	

348	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**
	Application Form Dy. No / Tracking ID & date of submission	(394-XPP-1P8U, 2024-10-25)
	Detail of Fee Submitted	75000.0, 2024-10-14,
	The proposed proprietary name / brand name	**IBUTEMOL 48MG/160MG ORAL SUSPENSION**
	Label Claim	Each 5ml contains: Ibuprofen.....48mg Paracetamol.....160mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60ml, 120ml/As per S-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30OC at a dry place, protect from light and heat.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Analgesic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Hubei Biocause Heilen Pharmaceutical Co., Ltd,M/s Zafa Chemie API Ltd
	Detail of stability batches of drug product	3 batches of 100 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC attested invoice is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE against ADOBIL 160 MG/48 MG / 5 ML PERORALNA SUSPENZIJA BY SWIXX BIOPHARMA KFT, HUNGARY
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	For both paracetamol and Ibuprofen as per zone IV-A conditions
	The status in reference regulatory authorities	1. Combofen for children 32 mg/ml + 9.6 mg/ml oral suspension (Hungary for Slovenia); 2. Combofen Za djecu 32 mg/ml + 9,6 mg/ml Oral Suspension (Spain for Croatia); 3. Tachifenekid 32 mg/ml + 9.6 mg/ml oral suspension (Spain for Malta)
	GMP status of the firm	GMP certificate based on evaluation conducted on 14-12-2023
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
349	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**Biogen Life Sciences** 8-KM, Chak Beli Road, Rawat, **(000911)**
	Application Form Dy. No / Tracking ID & date of submission	(7YM-VX6-DW7B, 2024-10-29)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	**Bi-Set 4mg Injection**
	Label Claim	Each 2ml contains: Ondansetron 4mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	2ml x5's, 2ml x 1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Condition
	For generic drugs (me-too Status)	Pharmedic Laboratories Onset 4mg Injection
	Pharmacotherapeutic Group of (API)	5HT3 receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. SONIA ORGANIC CO. LTD No.11/2, Attibele Industrial Aera, Balagaranahalli Village, AnekalTaluk, Bengaluru Rural District-5600004 Karnataka India. Phone : 080-26607568 E-Mail: admin@Soniaorganics.com
	Detail of stability batches of drug product	3 batches of 2000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Ms Bio Mark without timely intimation to DRAP; hence, may be verified accordingly
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE against onset 4mg injection
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	as per zone IV-A conditions
	The status in reference regulatory authorities	ZOFRAN 4mg Injection Approved by: USFDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has borrowed API from Ms Bio Mark without timely intimation to DRAP; hence, may beverified accordingly. Moreover, the firm has submitted GMP certificate of API valid at the time ofsubmission but is expired now, hence, valid GMP certificate shall be submitted before issuance ofregistration letter.	
	Decision	
	Approved The firm shall submit the following before issuance of registration letter: i. copies of valid GMP and DML of the applicant ii. API loan verification.	
350	Case Category	Routine (Sabahat Zehra)
	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	(W67-VRJ-SYU3, 2026-02-23)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**MYZOLE ORAL DRENCH**
	Label Claim	EACH 100ML CONTAINS:- BITHIONOL SULFOXIDE.....10 GM LEVAMISOL HYDROCHLORIDE.....1.5GM
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Year(s)at Room Temperature
	For generic drugs (me-too Status)	BITHNISOL ORAL DRENCH (REG NO. 063677)

	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
351	Case Category	Routine (Sabahat Zehra)
	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	(V58-V5P-28GD, 2026-02-23)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**BENTAZOLE ORAL DRENCH**
	Label Claim	Each 5ml contains:- Closantel.....250 mg Mebendazole ..... 375mg. (As per innovator's specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	CLOMEB SUPER ORAL DRENCH (REG NO. 041284)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
352	Case Category	Routine (Sabahat Zehra)
	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	(3GX-ZRL-8XSN, 2026-02-23)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**THIAZOLE ORAL SUSPENSION**
	Label Claim	Each 100ml contains: Thiabendazole USP..... 13.3% (USP specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Year(s)at Room Temperature
	For generic drugs (me-too Status)	THIABAK ORAL SUSPENSION (REG NO. 062178)
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
353	Case Category	Routine (Sabahat Zehra)
	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	(GGR-6L4-MQ86, 2026-02-23)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**PEPTOREX ORAL SOLUTION**
	Label Claim	Each ml contains:- Sulphadimidine.....35mg. Sulphadiazine.....36mg. Streptomycin sulphate..7.6mg. Neomycin sulphate...1.8mg. Sodium chloride.....11.33mg. Calcium glucoate.....2.2mg. Magnesium sulphate...0.6mg. Potassium chloride.....3.6mg. Kaolin.....103.33mg. Pectin.....7.1mg. Glycine.....20.9mg. (As Per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ml 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature

	For generic drugs (me-too Status)	NO-SCOUR ORAL SUSPENSION (REG NO. 072673)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Formulation contains four antibiotics, under review of sub-committee on veterinary drugs.	
	Decision	
	Deferred Deferred for submission of valid RRA references in support of their product, if available.	
354	Case Category	Routine (Sabahat Zehra)
	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	(GVN-VH6-RR21, 2026-02-22)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**VALBAZEN 10% ORAL SUSPENSION**
	Label Claim	Each 100ml contains: Albendazole..... 10 g (USP specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	HANZOLE 10% ORAL SUSLPENSION (REG NO. 102253)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
355	Case Category	Routine (Sabahat Zehra)

	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	(3VB-7N2-89B3, 2026-02-22)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**RICO ZOLE 15% ORAL SUSPENSION**
	Label Claim	Each 100ml contains: Ricobendazole ..... 15 gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	RICOZOLE-C SUSPENSION (REG NO. 033249)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
356	Case Category	Routine (Sabahat Zehra)
	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	(Q2W-1G4-81ZD, 2026-02-22)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**MISOLE GOLD SUSPENSION**
	Label Claim	Each 100 ml contains: Levamisole HCl.....1.500 gm Cobalt Sulphate.....0.382 gm Sodium Selenite.....0.050 mg (As Per innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	VERNIL SC DRENCH (REG NO. 033261)
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
357	Case Category	Routine (Sabahat Zehra)
	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	(B6Z-R14-RB3E, 2026-02-22)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**MAX VET ORAL SUSPENSION**
	Label Claim	Each ml Contains:- Triclabendazole.... 50mg. Ivermectin ..... 1mg. Fenbendazole... 50mg. (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	TRIVERFEN DRENCH. (REG NO. 049627)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
358	Case Category	Routine (Sabahat Zehra)
	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	(PL4-E7X-SQGH, 2026-02-22)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**VALBAZEN 2.5% ORAL SUSPENSION**
	Label Claim	Each 100ml contains: Albendazole..... 2.5 g USP (specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	HANZOLE 2.5% ORAL SUSLPENSION (REG NO. 102251)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
359	Case Category	Routine (Sabahat Zehra)
	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	(N3L-DU6-NAXM, 2026-02-22)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**IVEZEN DRENCH**
	Label Claim	Each ml contains: Ivermectin (B.P)..... 10 mg (As per Innovator's Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	IVOTEK DRENCH (REG NO. 063601)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The

		Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
360	Case Category	Routine (Sabahat Zehra)
	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	(J2H-9D1-B653, 2026-02-22)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**INTERZOLE 19.5% ORAL SUSPENSION**
	Label Claim	Each ml contains: Triclabendazole..... 50 mg Levamisole as HCl.....37.5 mg Cobalt Sulphate.....0.075 mg Sodium Selenite.....0.035 mg (As Per innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	LEVA BALT ORAL SUSLPENSION (REG NO. 103903)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
361	Case Category	Routine (Sabahat Zehra)
	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	(5DT-ETR-6LH4, 2026-02-22)

	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**INTERZAN ORAL SUSPENSION**
	Label Claim	Each 100ml contains: Oxyclozanide..... 3 g Levamisole HCl.....1.5 g Cobalt chloride.....0.075 g Sodium Selenite.....0.035 g (As Per innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	COBAZASOL-PL ORAL SUSLPENSION (REG NO. 102246)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
362	Case Category	Routine (Sabahat Zehra)
	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	(SM4-LYX-4M6L, 2026-02-22)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**FENOX DRENCH**
	Label Claim	Each 100ml contains: Oxyclozanide..... 6.25 g Oxfendazole.....2.265 g Cobalt Sulphate .....0.167 g Sodium Selenite.....0.050 g (As Per innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	PUNCH DRENCH (REG NO. 032206)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
363	Case Category	Routine (Sabahat Zehra)
	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	(N2E-Z93-E6PB, 2026-02-22)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**CYPERTHRIN LIQUID**
	Label Claim	Each ml contains: Cypermethrin..... 10% W/V
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Year(s)at Room Temperature
	For generic drugs (me-too Status)	ECTORID SOLUTION DISINFECTANT (RE G NO. 078372)
	Pharmacotherapeutic Group of (API)	Ectoparasiticide
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The manufacturer didn't have topical section(vet) and has confirmed that the product will be manufacturer in oral liquid section (Vet).	
	Decision	
	Rejected The instant case is rejected on the grounds that requisite facilities for the manufacture of the topical formulation is not available.	
364	Case Category	Routine (Sabahat Zehra)
	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	(8P7-6AR-S8W9, 2026-02-22)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**METHRIN LIQUID**
	Label Claim	Each ml contains: Deltamethrin..... 25 mg (BP specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Year(s)at Room Temperature
	For generic drugs (me-too Status)	TRIVERFEN DRENCH. (REG NO. 049627)
	Pharmacotherapeutic Group of (API)	Insectiside
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	Preset
	Evaluation Remarks	
	The manufacturer didn't have topical section(vet) and has confirmed that the product will be manufacturer in oral liquid section (Vet).	
	Decision	
	Rejected The instant case is rejected on the grounds that requisite facilities for the manufacture of the topical formulation is not available.	
365	Case Category	Routine (Sabahat Zehra)
	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	(MGN-L4M-WUAE, 2026-02-23)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**CURAZOLE ORAL SUSPENSION**
	Label Claim	Each 100ml contains: FENBEDAZOLE..... 10 g (BP specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	FENBAK 10 ORAL SUSPENSION (REG NO. 034554)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices

		(GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
366	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	(G7W-P3P-DSTA, 2026-01-14)
	Detail of Fee Submitted	38700, 2026-01-13,
	The proposed proprietary name / brand name	**Highnorc oral Liquid**
	Label Claim	Each 100ml Contains: Norfloxacin HCL.....20gm Colistin Sulphate...60 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000-De-Controlled,25-De-Controlled,5-De-Controlled,500-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 C ROLD ORAL LIQUID
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	PASS
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
367	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	(JJT-113-AL1M, 2026-01-14)
	Detail of Fee Submitted	38700, 2026-01-13,
	The proposed proprietary name / brand name	**DOXY PLUS GRANULES**
	Label Claim	Each 1Kg contains: Tylosin Tartrate.....10% Doxycycline .....20% Bromhexine 0.5%
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100G-De-Controlled,1KG-De-Controlled,500G-De-Controlled,5KG-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)	MYCOHIL GRANULES
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	PASS
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 kg pack size.	
368	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	(UJR-DDW-DVV6, 2026-01-14)
	Detail of Fee Submitted	38700, 2026-01-13,
	The proposed proprietary name / brand name	**AMINOR ORAL LIQUID**
	Label Claim	Each 100 ml contains: Norfloxacin.....20g Aminophyllin.....8g Guaiphenesin 20g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000-De-Controlled,25-De-Controlled,5-De-Controlled,500-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 PLUS 20% ORAL LIQUID Reg#033241
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	PASS
	Evidence of approval of manufacturing facility	present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
369	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	(8QP-Q72-Y6D9, 2026-01-14)
	Detail of Fee Submitted	38700, 2026-01-13,
	The proposed proprietary name / brand name	**ACETYL ORAL LIQUID**
	Label Claim	Each 100ml contains:- Norfloxacin.....10% Colistin Sulphate.....250MIU Tylosin tartrate.....5%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ML-De-Controlled,25L-De-Controlled,500ML-De-Controlled,5L-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)	NORCOTYL SOLUTION Reg#071021
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	PASS
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
370	Case Category	Routine (Saima Hussain)
	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	(RDH-7W3-UNHB, 2024-08-15)
	Detail of Fee Submitted	75000.0, 2024-07-10,
	The proposed proprietary name / brand name	**FINEREN Tablets 10mg**
	Label Claim	Each Film Coated Tablet Contains : Finerenone .....10mg (Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Gansu Hanju Pharmaceutical Co Ltd. -China
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Kerendia Tablets approved by FDA for Bayer HealthCare Pharmaceuticals Inc.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
371	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. Registration Board in its 353rd meeting decided as under: 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. Firm in their response informed that, they are submitting the public assessment report (Pharmaceutical Interview Form) available on PMDA Website on following
link: https://www.pmda.go.jp/PmdaSearch/iyakuDetail/GeneralList/3949005 Along with physiochemical properties and solubility characterization provided by API Manufacturer in its open part of DMF. Justification for Dissolution Condition: The Public Assessment Report specifies the dissolution conditions for the innovator product as follows: Dissolution Medium: Water Volume: 900 mL Apparatus: Paddle Rotation Speed: 50 rpm Sampling Time: 45 minutes Firm has revised the finished product specifications for dissolution test as given by the innovator and conducted the comparative dissolution studies as described in PMDA Document. Results observed in CDP performed are comparable to innovator product. Detailed comparative dissolution profile along with detailed results has been submitted. The firm has also submitted the RMP of the product along with RMP of innovator.

Decision

Deferred

The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points;

1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms.
2. Same R&D Manager (Ms. Naheed Yousaf) has signed documents of both firms.
3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms.
4. Same data logger sheets are submitted in cases of both firms.

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	(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. 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. Registration Board in its 353rd meeting decided as under: 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. Firm in their response informed that, they are submitting the public assessment report (Pharmaceutical Interview Form) available on PMDA Website on following

	link: https://www.pmda.go.jp/PmdaSearch/iyakuDetail/GeneralList/3949005 Along with physiochemical properties and solubility characterization provided by API Manufacturer in its open part of DMF. Justification for Dissolution Condition: The Public Assessment Report specifies the dissolution conditions for the innovator product as follows: Dissolution Medium: Water Volume: 900 mL Apparatus: Paddle Rotation Speed: 50 rpm Sampling Time: 45 minutes Firm has revised the finished product specifications for dissolution test as given by the innovator and conducted the comparative dissolution studies as described in PMDA Document. Results observed in CDP performed are comparable to innovator product. Detailed comparative dissolution profile along with detailed results has been submitted. The firm has also submitted the RMP of the product along with RMP of innovator.	
	Decision	
	Deferred The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points; 1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms. 2. Same R&D Manager (Ms. Naheed Yousaf) has signed documents of both firms. 3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms. 4. Same data logger sheets are submitted in cases of both firms.	
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	(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. 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. Registration Board in its 353rd meeting decided as under: 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. Firm in their response informed that, they are submitting the public assessment report (Pharmaceutical Interview Form) available on PMDA Website on following
link: https://www.pmda.go.jp/PmdaSearch/iyakuDetail/GeneralList/3949005 Along with physiochemical properties and solubility characterization provided by API Manufacturer in its open part of DMF. Justification for Dissolution Condition: The Public Assessment Report specifies the dissolution conditions for the innovator product as follows: Dissolution Medium: Water Volume: 900 mL Apparatus: Paddle Rotation Speed: 50 rpm Sampling Time: 45 minutes Firm has revised the finished product specifications for dissolution test as given by the innovator and conducted the comparative dissolution studies as described in PMDA Document. Results observed in CDP performed are comparable to innovator product. Detailed comparative dissolution profile along with detailed results has been submitted. The firm has also submitted the RMP of the product along with RMP of innovator.

Decision

Deferred

The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points;

1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms.
2. Same R&D Manager (Ms. Naheed Yousaf) has signed documents of both firms.
3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms.

4. Same data logger sheets are submitted in cases of both firms.

374

Case Category	Routine (Saima Hussain)
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	(6QG-D8Z-32U3, 2024-03-15)
Detail of Fee Submitted	30000.0, 2024-02-07,
The proposed proprietary name / brand name	**Briva Tablet 25mg**
Label Claim	Each Film coated tablet contains: Brivaracetam 25mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Protect from Heat light and moisture
For generic drugs (me-too Status)	Brivace 25mg Tablet (Hilton Pharma)
Pharmacotherapeutic Group of (API)	Anti-Convulsant
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 Contact person: Manna Chen Title:Sales Manager Tel: +86-28-86136736 Fax
Detail of stability batches of drug product	Stability data of batches RD-GP-5D-BR-23007, RD-GP-5D-BR-23008,RD-GP-5D-BR-23009 2500 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted by the firm.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has been performed against the product (Briviact 25mg Film coated 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	Reference Regulatory Authority: U.S. FDA Manufacturer name: UCB Pharma Limited Brand name: Briviac
GMP status of the firm	GMP certificate dated 06-06-2022 is submitted by the firm.
Evidence of approval of manufacturing facility	GMP certificate dated 06-06-2022 mentioned that firm has tablet section.

Evaluation Remarks

Sr.no.	Observations/Shortcomings	Response of the Firm
1.	You are advised to revise the finished product specification in accordance with the British Pharmacopoeia (BP) official monograph for Brivaracetam Tablets, as it is now available in the BP 2025 edition. Accordingly, submit a performance report of the drug product based on the revised	(We acknowledge the availability of the official British Pharmacopoeia (BP) monograph for Brivaracetam Tablets in the BP 2025 edition. Accordingly, we will revise the finished product specification in line with the requirements of the updated monograph. As the sample of Brivaracetam Tablets 25 was

		specification, conducted at the next scheduled time point of the ongoing stability study.	charged on stability on 8 May,2023 and Stability of 24 month is Completed on 8 May,2025. A performance report for the drug product, based on the updated specification, will be prepared and submitted using the commercial-scale batch to ensure compliance with the latest pharmacopoeial standards. Commitment is enclosed.)
	2.	Justify the use of a different HPLC assay method of drug substance by the drug product manufacturer than that recommended by the drug substance manufacturer, particularly considering the differences in mobile phase composition (TFA vs. phosphoric acid), column dimensions, absence of system suitability criteria, and lack of duplicate sample preparation in your method.	The analytical procedure outlined in the manufacturer's DMF for Brivaracetam was not implemented, as it is no longer current and has been revised. The Updated HPLC assay method used for the drug substance by the drug product manufacturer is consistent with the method recommended by the drug substance manufacturer.Updated Analytical Method of Brivaracetam Raw Material recommended by the Manufacturer is also attached.
	Decision of 350th meeting of Registration Board: The Registration Board directed the applicant to perform quality tests in accordance with the official British Pharmacopoeia (BP) monograph for Brivaracetam Tablets using the remaining samples of the trial batches, and to submit the performance report along with the corresponding raw data sheets and chromatograms. Firm submitted the stability data of newly manufactured three trial batches using the remaining quantity of API procured initially. Accordingly submit the complete analytical record performed in accordance with the official British Pharmacopoeia (BP) monograph for Brivaracetam Tablets.		
	Decision		
	Approved Firm shall submit fee for pre-registration variation as the latest fee SRO prior the issuance of Registration Letter.		

375	Case Category	Export Facilitation (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	(32S-RTA-Z2XT, 2026-02-03)
	Detail of Fee Submitted	37000.0, 2025-01-28,
	The proposed proprietary name / brand name	**Bemtec-E**
	Label Claim	Each film-coated tablet contains: Bempedoic Acid.....180mg 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)	2 YearStore below 30 degree centigrade
	For generic drugs (me-too Status)	BemPex-Z 180mg/10mg Tablet
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	IND-Swift Laboratories Limited,Metrochem API 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	Nustendi 180mg Tablet
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Firm shall submit fee for pre-registration variation as the latest fee SRO prior the issuance of Registration Letter.	
376	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	**MTI MEDICAL (PVT.) LTD** Plot 586-587, Sundar Industrial Estate, Lahore **(000801)**
	Application Form Dy. No / Tracking ID & date of submission	(GME-BGS-713J, 2025-07-15)
	Detail of Fee Submitted	37000.0, 38000.0 2025-05-22, 2025-06-27
	The proposed proprietary name / brand name	**Trolenda Injection 20mg**
	Label Claim	Each vial contains Dantrolene sodium 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25 C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Scinopharm Taiwan Limited
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Scinopharm Taiwan Limited
	Detail of stability batches of drug product	Attached in module 3
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in module 1
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in module 3
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in module 2 and 3
	The status in reference regulatory authorities	Revonto Lyophilized Injection 20mg, Approved by FDA Company: DSM Pharmaceuticals, Greenville, NC 27834
	GMP status of the firm	Attached in module 1
	Evidence of approval of manufacturing facility	Attached in module 1
	Evaluation Remarks	

Sr.no.	Shortcomings	Response of the Firm

	1.	Submit the Open Part of the Drug Master File (DMF) of the API on the official letterhead of the API manufacturer, duly signed and endorsed by the authorized representative of the API manufacturer, since the submitted DMF is neither signed nor endorsed.	Firm replied that ScinoPharm Taiwan, Ltd. is an FDA-approved API manufacturer/source (as an evidence firm submitted the letter from USFDA in the name of API manufacturer dated 08-06-2019 mentioned that the U.S. Food and Drug Administration (FDA) conducted an inspection at ScinoPharm Taiwan Ltd, FEI:3002840477, located at No. 1, Nan-Ke 8th Road, Shan-Hua, Tainan 74144, Taiwan from 05/13/2019 - 05/17/2019. FDA has determined that the inspection classification of this facility is "no action indicated" ('NAI')1. Based on this inspection, this facility is considered to be in an acceptable state of compliance with regards to current good manufacturing practice (CGMP). This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP). The supplier has not provided the requested signed and endorsed Open Part of the DMF directly to us. Therefore, the DMF Statement/Undertaking provided by ScinoPharm Taiwan, Ltd. is enclosed for reference. The FDA approval/verification details are also enclosed. If required, Sinopharm Taiwan, Ltd, located at No.1, Nan-Ke 8th Road, Shan-Hua, Tainan 741014, Taiwan, hereby confirm and undertake that we shall submit the Drug Master File (DMF) for Dantrolene Sodium directly to the Drug Regulatory Authority of Pakistan (DRAP) upon Agency's formal request.
	2.	Submit purchase records/invoices as documentary evidence of procurement of the reference (innovator) product pack used in the comparative studies.	The documentary evidence for procurement of the reference (innovator) product used in the comparative studies is enclosed. The Import Authorization/NOC in Kazakh language, previously submitted, is attached again for reference. Additionally, the invoice issued by Galaxy International to MTI Medical (Pvt.) Ltd., in both English and Kazakh languages, is enclosed. The reference product vials were brought from Kazakhstan to Pakistan in May 2026 by Mr. Nurmukhanbetov Gani, Director of MTI Medical (Pvt.) Ltd. The relevant travel ticket is also enclosed as supporting evidence. Galaxy International is Mr. Gani's associated company in Kazakhstan through which export-related transactions are handled. The above documents collectively provide evidence of the procurement and import/receipt of the reference product used in the comparative studies.
	Decision		
	Approved Registration letter will be issued upon submission of Open Part of the DMF duly signed and endorsed by the authorized representative of the API manufacturer.		
377	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	(SR1-S82-LGZU, 2026-02-24)
Detail of Fee Submitted	75000, 2025-09-17,
The proposed proprietary name / brand name	**Lembex 10mg Tablet**
Label Claim	Each Film Coated Tablet Contains: Lemborexant.....10mg (As per Innovator's specifications)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	3 x 10's-As per SRO
Shelf Life (Unit)	2 YearStore at 20ºC to 25ºC (68ºF to 77ºF); excursions permitted from 15ºC to 30ºC (59ºF to 86ºF)
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Dual Orexin Antagonist
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd.
Detail of stability batches of drug product	40°C ± 2°C / NMT 75% RH, 30°C ± 2°C / 65% RH ± 5%
Documents for the procurement of API with approval from DRAP (in case of Import)	No. of license: DIL-C-0C344D
Pharmaceutical Equivalence and Comparative Dissolution Profile	Lembex 10mg Tablet with DAYVIGO 10mg Tablet
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	40°C ± 2°C / NMT 75% RH, 30°C ± 2°C / 65% RH ± 5%
The status in reference regulatory authorities	Registered drug by US FDA (DAYVIGO (Lemborexant) tablets, for oral use)
GMP status of the firm	Issuance date: 07-04-2025 Valid Date: 06-04-2028
Evidence of approval of manufacturing facility	000427

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	Submit the Open Part of the Drug Master File (DMF) for the API on the official letterhead of the API manufacturer, duly signed and endorsed by the authorized representative/personnel of the API manufacturer.	Firm submitted open Part of the Drug Master File (DMF) for the API on the official letterhead of the API manufacturer. Email from the API manufacturer's authorized person has also been forwarded to the official mailing address of secretary Registration Board as evidence that DMF is supplied by authorized person of company.
2.	Submit clear photographs of the innovator product pack used in the comparative studies, along with the corresponding purchase records.	Photographs of the innovator product pack used in the comparative studies, along with the corresponding purchase records (pharmacy invoice is submitted) have been submitted.
3.	Submit a valid drug substance-specific GMP certificate for the API manufacturer.	Firm submitted the valid drug substance specific GMP certificate of the API manuafcturer.

Decision

Deferred

	The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points; 1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms. 2. Same R&D Manager (Ms. Naheed Yousaf) has signed documents of both firms. 3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms. 4. Same data logger sheets are submitted in cases of both firms.	
378	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	(JQJ-P7N-PEME, 2026-02-24)
	Detail of Fee Submitted	75000, 2025-09-17,
	The proposed proprietary name / brand name	**Lembex 5mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Lemborexant.....5mg (As per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's-As per SRO
	Shelf Life (Unit)	2 YearStore at 20ºC to 25ºC (68ºF to 77ºF); excursions permitted from 15ºC to 30ºC (59ºF to 86ºF)
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	dual orexin antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	40°C ± 2°C / NMT 75% RH, 30°C ± 2°C / 65% RH ± 5%
	Documents for the procurement of API with approval from DRAP (in case of Import)	No. of license: DIL-C-0C344D
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lembex 5mg Tablet with DAYVIGO 5mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	40°C ± 2°C / NMT 75% RH, 30°C ± 2°C / 65% RH ± 5%
	The status in reference regulatory authorities	Registered drug by US FDA (DAYVIGO (Lemborexant) tablets, for oral use)
	GMP status of the firm	Issuance date: 07-04-2025 Valid Date: 06-04-2028
	Evidence of approval of manufacturing facility	000427
	Evaluation Remarks	
	DAYVIGO (lemborexant) tablets, for oral use, [controlled substance schedule pending] Initial U.S. Approval: [pending controlled substance scheduling] INDICATIONS AND USAGE:DAYVIGO is an orexin receptor antagonist indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. DOSAGE AND ADMINISTRATION Recommended dose is 5 mg taken no more than once per night, immediately before going to bed, with at least 7 hours remaining before the planned time of awakening. Dosage may be increased to 10 mg based on clinical response and tolerability. The maximum recommended dose is 10 mg once daily. Time to sleep onset may be delayed if taken with or soon after a meal. Hepatic Impairment: o Moderate hepatic impairment: Initial and	

maximum recommended dosage is 5 mg no more than once per night. o Severe hepatic impairment: Not recommended.

Sr.no.	Shortcomings	Response of the Firm
1.	Submit the Open Part of the Drug Master File (DMF) for the API on the official letterhead of the API manufacturer, duly signed and endorsed by the authorized representative/personnel of the API manufacturer.	Firm submitted open Part of the Drug Master File (DMF) for the API on the official letterhead of the API manufacturer. Email from the API manufacturer's authorized person has also been forwarded to the official mailing address of secretary Registration Board as evidence that DMF is supplied by authorized person of company.
2.	Submit clear photographs of the innovator product pack used in the comparative studies, along with the corresponding purchase records.	Photographs of the innovator product pack used in the comparative studies, along with the corresponding purchase records (pharmacy invoice is submitted) have been submitted.
3.	Submit a valid drug substance-specific GMP certificate for the API manufacturer.	Firm submitted the valid drug substance specific GMP certificate of the API manufacturer.

Decision

Deferred

The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points;

1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms.
2. Same R&D Manager (Ms. Naheed Yousaf) has signed documents of both firms.
3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms.
4. Same data logger sheets are submitted in cases of both firms.

379

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	(M7H-2MB-UH76, 2026-05-21)
Detail of Fee Submitted	75000, 2026-01-28,
The proposed proprietary name / brand name	**Gedaa 750mg Tablet**
Label Claim	Each Film Coated Tablet Contains: Gepotidacin Mesylate Dihydrate equivalent to Gepotidacin.....750mg (As per Innovator’s specifications)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	2 x 10's-As per SRO
Shelf Life (Unit)	2 YearStore at 20˚C to 25˚C (68˚F to 77˚F).
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Triazaacenaphthylene bacterial type II topoisomerase inhibitor
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd.
Detail of stability batches of drug product	40°C ± 2°C / NMT 75% RH, 30°C ± 2°C / 65% RH ± 5%

Documents for the procurement of API with approval from DRAP (in case of Import)	DIL-C-5E7179
Pharmaceutical Equivalence and Comparative Dissolution Profile	Gedaa 750mg Tablet with BLUJEPA 750mg Tablet
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	25°C ± 2°C / 65% ± 5% RH, 5°C ± 3°C
The status in reference regulatory authorities	Registered drug by US-FDA BLUJEPA (gepotidacin) tablets, for oral use.
GMP status of the firm	Issuance date: 07-04-2025 Valid Date: 06-04-2028
Evidence of approval of manufacturing facility	000427

Evaluation Remarks

INDICATIONS AND USAGE BLUJEPA is a triazaacenaphthylene bacterial type II topoisomerase inhibitor indicated for the treatment of female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms (kg) with uncomplicated urinary tract infections (uUTI) caused by the following susceptible microorganisms: Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, and Enterococcus faecalis.Usage to Reduce Development of Drug-Resistant Bacteria .To reduce the development of drug-resistant bacteria and maintain the effectiveness of BLUJEPA and other antibacterial drugs, BLUJEPA should be used only to treat infections that are proven or strongly suspected to be caused by bacteria. DOSAGE AND ADMINISTRATION • The recommended dosage of BLUJEPA is 1,500 mg (two 750 mg tablets) taken orally, twice daily (approximately 12 hours apart), for 5 days. • Administer BLUJEPA tablets after a meal to reduce the possibility of gastrointestinal intolerance.

Sr.no.	Shortcomings	Response of the Firm
1.	Submit the Open Part of the Drug Master File (DMF) for the API on the official letterhead of the API manufacturer, duly signed and endorsed by the authorized representative/personnel of the API manufacturer.	Firm submitted the Open Part of the Drug Master File (DMF) of API on the official letterhead of the API manufacturer. Furthermore, the DMF was also directly forwarded to the official mailing address of the Secretary, Registration Board, by the authorized representative of the API manufacturer.
2.	Submit clear photographs of the innovator product pack used in the comparative studies, along with the corresponding purchase records.	Photographs of the innovator product pack used in the comparative studies, along with the corresponding purchase records (pharmacy invoice) have been submitted.
3.	Submit a valid drug substance-specific GMP certificate for the API manufacturer.	Firm submitted the valid drug substance specific GMP certificate of the API manufacturer.

Decision

Deferred

The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points;

	1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms. 2. Same R&D Manager (Ms. Naheed Yousaf) has signed documents of both firms. 3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms. 4. Same data logger sheets are submitted in cases of both firms.	
380	Case Category	New Molecule/Formulation (Saima Hussain)
	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	(SPT-UB1-Z3V9, 2026-02-04)
	Detail of Fee Submitted	75000, 2026-01-30,
	The proposed proprietary name / brand name	**ATRIDE 0.75MG TABLETS**
	Label Claim	Each film coated tablet contains: Atrasentan HCl 0.803 mg eq. to Atrasentan.....0.75mg
	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,5's-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature between 68°F to 77°F (20°C to 25°C).
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Highly selective endothelin A (ETA) receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMATECH CO., LTD NO.11, CHONGQING ROAD, BAIYIN DISTRICT, BAIYIN CITY, GANSU PROVINCE, CHINA
	Detail of stability batches of drug product	115T25, 116T25, 117T25
	Documents for the procurement of API with approval from DRAP (in case of Import)	GANSU HAOTIAN PHARMATECH CO., LTD NO.11, CHONGQING ROAD, BAIYIN DISTRICT, BAIYIN CITY, GANSU PROVINCE, CHINA
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long term: 30oC ± 2oC and 65% ± 5% RH , Accelerated: 40oC ± 2oC and 75% ± 5% RH
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Section Approval attached.
	Evaluation Remarks	
	INDICATIONS AND USAGEVANRAFIA is an endothelin receptor antagonist indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g. This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether VANRAFIA slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial. WARNING: EMBRYO-FETAL TOXICITY See full prescribing information for complete boxed warning. • VANRAFIA may cause major birth defects if used during pregnancy • Exclude pregnancy before start of treatment. • Use effective contraception before	

start of treatment, during treatment and two weeks after treatment. • Discontinue VANRAFIA if pregnancy occurs.

Sr.no.	Shortcomings	Response of the Firm
1.	Submit the Open Part of the Drug Master File (DMF) of API on the official letterhead of the API manufacturer, duly signed and endorsed by the authorized representative of the API manufacturer, since the submitted DMF is neither signed nor endorsed.	Firm submitted the Open Part of the Drug Master File (DMF) of API on the official letterhead of the API manufacturer, duly signed and endorsed by the authorized representative of the API Manufacturer.
2.	Submit a valid 21 CFR compliance certificate for the computerized analytical system, along with a clear and legible copy of the audit trail.	Submitted
3.	Submit a valid, drug substance specific GMP Certificate of the API manufacturer, issued by the competent provincial regulatory authority of China.	Firm submitted the valid, drug substance specific GMP Certificate of the API manufacturer.

Decision

Approved

Firm shall submit fee for pre-registration variation as the latest fee SRO prior the issuance of Registration Letter.

381

Case Category	Routine (Sara Mehreen)
Name, address of Applicant.	**Univet Pharmaceuticals** 14-km adyala Road, Rawalpindi **(000424)**
Application Form Dy. No / Tracking ID & date of submission	(1H1-68M-SSQL, 2025-11-17)
Detail of Fee Submitted	38700, 2025-11-11,
The proposed proprietary name / brand name	**UNIDIN-98% ORAL POWDER**
Label Claim	Each kg contains: Amantadine HCl BP.....980g
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100gm,250gm,500gm& 1000gm-De-Controlled
Shelf Life (Unit)	2 Year(s)below 30c
For generic drugs (me-too Status)	Vet Amantex
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	GMP GRANTED
Evidence of approval of manufacturing facility	

Evaluation Remarks

Firm was asked to provide Target Species and they replied as following: "Unidin 98% powder is versatile veterinary formulation that provides targeted health benefits across diverse species, primarily supporting poultry like chickens, Turkeys & ducks in resisting devastating respiratory outbreaks such as Avian Influenza and new castle disease. Beyond Avian care the medication is extended to livestock herds, helping pigs overcome Swine infectious Gastroenteritis and complex respiratory issues, while protecting cattle and calves against early stage viral infection". Submitted for consideration of the Board, please.

Decision

Rejected

	The Registration Board after through deliberation decided to reject the case as firm applied Amantadine for use in Poultry & Livestock as cattle & calves.	
382	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	(DSA-H2X-WPWR, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**TROX-34 INJECTION**
	Label Claim	EACH ML CONTAINS: - Nitroxynil BP.....340mg. (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	TRONOX- 340 INJECTION. (099041)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
383	Case Category	Routine (Sara Mehreen)
	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	(JBS-EVV-7MJV, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**Neo-Cin W/S Powder**
	Label Claim	Each KG contains Neomycin Sulphate BP..... 1000GM (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000g-De-Controlled,100g-De-Controlled,150G-De-Controlled,250g-De-Controlled,500g-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	NEO-TIC-100 ORAL WATER SOLUBLE POWDER (122572) AAMSTER LABORATORIES, RAWAT, ISLAMABAD.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	Panel Inspection for grant of drug manufacturing licence(by way of formulation)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
384	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Vetz Pharmaceutical Pvt Ltd** Plot No. Q-1, Site Kotri, Sindh **(000813)**
	Application Form Dy. No / Tracking ID & date of submission	(ABZ-TPV-RLPV, 2025-08-29)
	Detail of Fee Submitted	38700.0, 2025-08-22,
	The proposed proprietary name / brand name	**Norvetz Oral Liquid**
	Label Claim	Each 100ml Contains: Norfloxacin USP.....20 gm Aminophylline BP.....8 gm Guaifenesin BP..... 20 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,1Lit-De-Controlled,250ml-De-Controlled,30ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled,5Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C and Protect from light and moisture.
	For generic drugs (me-too Status)	NOR+AG Oral solution
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In conclusion of the inspection it is interpreted that the management was focused /committed towards continous improvement and intends to extend its operations to effectively contribute in export markets while serving with good quality products availabili
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
385	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Vetz Pharmaceutical Pvt Ltd** Plot No. Q-1, Site Kotri, Sindh **(000813)**
	Application Form Dy. No / Tracking ID & date of submission	(83L-849-LTRM, 2025-09-03)
	Detail of Fee Submitted	38700.0, 2025-08-22,
	The proposed proprietary name / brand name	**Norvetz DS Oral Liquid**
	Label Claim	Each 100ml Contains: Norfloxacin USP.....10 gm Tylosin Tartrate BP.....5 gm Colistin Sulphate BP..... 250 MIU
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100ml-De-Controlled,1Lit-De-Controlled,250ml-De-Controlled,30ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled,5Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C and Protect from light and moisture.
	For generic drugs (me-too Status)	Norcotyl Oral solution
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In conclusion of the inspection it is interpreted that the management was focused/committed towards continuous improvement and intends to expand its operations to effectively contribute in Export markets while serving with good quality products availabili
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
386	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Vetz Pharmaceutical Pvt Ltd** Plot No. Q-1, Site Kotri, Sindh **(000813)**
	Application Form Dy. No / Tracking ID & date of submission	(36R-1Z7-HMVT, 2025-10-28)
	Detail of Fee Submitted	38700, 2025-10-23,
	The proposed proprietary name / brand name	**ANC-Vetz Oral Powder**
	Label Claim	Each 1000 gram powder contains: Amoxicillin as Trihydrate (BP): 100gm Colistin Sulphate (BP) 50gm Neomycin Sulphate 200gm (As per Innovator's specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,1kg-De-Controlled,25kg-De-Controlled,5 kg-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C and Protect from light and moisture.
	For generic drugs (me-too Status)	NC- Mox Powder
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	In conclusion of the inspection it is interpreted that the management was focused/committed towards continuous improvement and intend to expand its operations to effectively contribute in Export Markets while serving with good quality products availabili
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

Drug Regulatory Authority of Pakistan

(Pharmaceutical Evaluation & Registration Division)

******

Registration Board 361 Meeting Additional/Supplementary Minutes:

Sr. No	Title	Description
1	Case Category	Priority As Per 257-M of RB (Anam Saeed)
	Name, address of Applicant.	**Himmel Pharmaceuticals Private Limited** Ground Floor, 6- Judicial Colony phase-1 (Ext.) Shahrah Nazaria e Pakistan, **(05-352-0065-016174D)**
	Application Form Dy. No / Tracking ID & date of submission	(G51-HN3-TJ8R, 2026-08-20)
	Detail of Fee Submitted	313500, 2026-07-24,
	The proposed proprietary name / brand name	**Stoboclo**
	Label Claim	Each pre-filled syringe contains 60 mg of denosumab in 1 mL of solution (60 mg/mL).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 pre-filled syringe with safety guard.-As per SRO
	Shelf Life (Unit)	24 Month(s)Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the pre-filled syringe in the outer carton in order to protect from light.
	For generic drugs (me-too Status)	Prolia Injection 60mg/mL (Reg. No. 077527)
	Pharmacotherapeutic Group of (API)	Drugs for treatment of bone diseases – Other drugs affecting bone structure and mineralisation, human monoclonal antibody (IgG2) ATC code: M05BX04
	Name, address of Manufacturing site:	CELLTRION Pharm, Inc. -82, 2 Sandan-ro, Ochang-eup, Cheongwongu, Cheongju, Chungcheongbuk-do, 28117, Republic of Korea-South Korea
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilar to Prolia
	Name, address of Marketing Authorization Holder:	CELLTRION, Inc, 23, Academy-ro, Yeonsu-gu, Incheon, 22014, Republic of Korea, South Korea
	Details of Certificates (CoPP/FSC/cGMP):	EMA approved COPP No. 01/26/005293 dated 20-05-2026 is submitted
	Details of Authorization Letter :	LOA provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	U. S. Food & Drug Administration
	Evaluation Remarks	
	The applied product is EMA approved vide Reg.No. EU/1/24/1905.	
	Decision	
	Approved	

	Keeping in view the approval status in EMA; Registration Board approved the product subject to: 1. Compliance of current Import Policy for finished drugs. 2. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 3. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 4. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
2	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(MEX-TXQ-X6U1, 2026-06-18)
	Detail of Fee Submitted	38700, 2026-02-16,
	The proposed proprietary name / brand name	**DENORIN 10000IU Anti-Xa/1ml Injection**
	Label Claim	Each vial (1ml) contains: Enoxaparin Sodium..... 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	De-regulated-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 15 to 30°C
	For generic drugs (me-too Status)	Clexane by Sanofi Aventis
	Pharmacotherapeutic Group of (API)	Low Molecular Weight Heparin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Accelerated (40C) for 06 months & Realtime (30C) for 6 months, Three Batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP clearance invoice no. RO-CF96B8 dated 04-09-2024.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Data in light of decision of 289th meeting is submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (40C) for 06 months & Realtime (30C) for 36 months, Three Batches
	The status in reference regulatory authorities	USFDA - LOVENOX
	GMP status of the firm	GMP Certificate based on inspection dated 01-07-2024.
	Evidence of approval of manufacturing facility	Section regularization letter dated 14-11-2025.
	Evaluation Remarks	
	.	
	Decision	
	Approved Registration Board approved the product.	
3	Case Category	New Section (M. Zubair Masood)
	Name, address of Applicant.	**Getz Pharma (Pvt) Limited** 29-30/27,Korangi Industrial Area karachi **(000284)**

	Application Form Dy. No / Tracking ID & date of submission	(SVV-JN4-GATH, 2026-08-20)
	Detail of Fee Submitted	75000, 2026-04-14,
	The proposed proprietary name / brand name	**Sem-O Tablets 25mg**
	Label Claim	Each tablet contains: Semaglutide.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	24 Year(s)Do not store above 30°C. Protect from sunlight and moisture.
	For generic drugs (me-too Status)	-
	Pharmacotherapeutic Group of (API)	GLP-1 receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Hubei JxBio Pharmaceutical Co., Ltd., No. 9, Lvshan Road, Xian'an Economic Development District, Xianning City, Hubei Province
	Detail of stability batches of drug product	Three Batches: 787DS01, Accelerated at 40C for 06 months and Real Time at 30C for 36 months. Batch Size: 1400 Tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP clearance no. E-11461452639712 dated 15-08-2025.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: C005-D210101, C005-D210201, C005-D210401 Accelerated at 2-8C for 06 months and Real Time at -20C for 36 months. Batch Size: 1476g, 1196g, 1063g
	The status in reference regulatory authorities	WEGOVY Tablets 25mg by M/s Novo Nordisk Inc. Plainsboro, USA.
	GMP status of the firm	GMP Certificate based on inspection dated 14-10-2025.
	Evidence of approval of manufacturing facility	Renewal of DML dated 13-05-2026.
	Evaluation Remarks	
	The firm already has registration of other strengths of tablets manufactured from API of same source.	
	Decision	
	Approved	
4	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**Bromed Animal Health** 246A, West Wood Colony **(05-352-0066-037660D)**
	Application Form Dy. No / Tracking ID & date of submission	(Z7M-DAY-84HY, 2024-11-07)
	Detail of Fee Submitted	300000.0, 2024-11-06,
	The proposed proprietary name / brand name	**CTCVAC YBBEN**
	Label Claim	Each dose contains; Low pathogenic avian influenza virus (LPAIV) rgHS314 strain(H9N2-)Y280 lineage (inactivated)..10^6.5EID50

		Infectious bronchitis virus (lBV) CV 001 strain, CE4 (inactivated) --- minimum of 10^6.5EID50 Infectious bronchitis virus (lBV) CV013 strain, CE4 (inactivated) --- minimum of 10^6.5EID50 Duck adenovirus (Egg drop syndrome) (inactivated) minimum of 10^8ElD50 Newcastle disease virus (NDV) LaSota strain (lnactivated) --- minimum of 10^9 EID50.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	500ml-De-Controlled
	Shelf Life (Unit)	24 Month(s)2-8°C
	For generic drugs (me-too Status)	Not registered
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	CTCVAC Co., Ltd-106, Saengmyeonggwahakgwan-gil, Hongcheon-eup, Hongcheon-gun, Gangwon-do, Republic of Korea-South Korea
	Name, address of Marketing Authorization Holder:	CTCVAC Co., Ltd, 106, Saengmyeonggwahakgwan-gil, Hongcheon-eup, Hongcheon-gun, Gangwon-do, Republic of Korea, South Korea
	Details of Certificates (CoPP/FSC/cGMP):	Valid legalized FSC & GMP has been submitted.
	Details of Authorization Letter :	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	
	EWG decided to give final opportunity to the firm to provide scientific studies regarding genetic and antigenic similarity of CV 001 & CV013 strains with existing strains of Pakistan.	
	Decision	
	Deferred Keeping in view recommendations of EWG; Registration Board decided to give final opportunity to the firm to provide scientific studies regarding genetic and antigenic similarity of CV 001 & CV013 strains with existing strains of Pakistan.	
5	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**Bromed Animal Health** 246A, West Wood Colony **(05-352-0066-037660D)**
	Application Form Dy. No / Tracking ID & date of submission	(PGH-27T-AQ3M, 2024-05-11)
	Detail of Fee Submitted	300000.0, 2024-04-26,
	The proposed proprietary name / brand name	**CTCVAC QX**
	Label Claim	Composition per one dose:Infectious Bronchitis Virus (K1277/03 P90 strain) ≥ 10^3.0EID50 / dose at release
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	2000Dose/Vial-De-Controlled
	Shelf Life (Unit)	24 Month(s)2-8°C
	For generic drugs (me-too Status)	Not registered
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	CTCVAC Co., Ltd.-106, Saengmyeonggwahakgwan-gil, Hongcheon-eup,

		Hongcheon-gun, Gangwon-do, Republic of Korea-South
	Name, address of Marketing Authorization Holder:	CTCVAC Co., Ltd., 106, Saengmyeonggwahakgwan-gil, Hongcheon-eup, Hongcheon-gun, Gangwon-do, Republic of Korea, South
	Details of Certificates (CoPP/FSC/cGMP):	Valid Legalized FSC & GMP has been submitted.
	Details of Authorization Letter :	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	
	EWG in its 12th meeting did not recommend the product for grant of registration as firm could not establish genetic and antigenic similarity of K1277/03 P90 strain with existing strains of Pakistan.	
	Decision	
	Rejected Keeping in view the recommendations of EWG; Registration Board did not acceded to request of firm for grant of registration as firm could not establish genetic and antigenic similarity of K1277/03 P90 strain with existing strains of Pakistan.	
6	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**Bromed Animal Health** 246A, West Wood Colony **(05-352-0066-037660D)**
	Application Form Dy. No / Tracking ID & date of submission	(LQ6-1L1-MX2Z, 2024-05-11)
	Detail of Fee Submitted	300000.0, 2024-04-26,
	The proposed proprietary name / brand name	**CTCVAC QXN**
	Label Claim	Composition per one dose: Newcastle Disease Virus (K148/08 strain) ≥ 10^6.0EID50 / dose, Infectious Bronchitis Virus (K1277/03 P90 strain) ≥ 10^3.0EID50 / dose
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	2000Dose/Vial-De-Controlled
	Shelf Life (Unit)	24 Month(s)2-8°C
	For generic drugs (me-too Status)	Not Registered.
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	CTCVAC Co., Ltd.-106, Saengmyeonggwahakgwan-gil, Hongcheon-eup, Hongcheon-gun, Gangwon-do, Republic of Korea-South
	Name, address of Marketing Authorization Holder:	CTCVAC Co., Ltd., 106, Saengmyeonggwahakgwan-gil, Hongcheon-eup, Hongcheon-gun, Gangwon-do, Republic of Korea, South
	Details of Certificates (CoPP/FSC/cGMP):	Valid legalized FSC & GMP certificate has been submitted.
	Details of Authorization Letter :	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	
	EWG in its 12th meeting did not recommend the product for grant of registration as firm could not establish genetic and antigenic similarity of K1277/03 P90 strain with existing strains of Pakistan.	

	Decision	
	Rejected Keeping in view the recommendations of EWG; Registration Board did not acceded to request of firm for grant of registration as firm could not establish genetic and antigenic similarity of K1277/03 P90 strain with existing strains of Pakistan.	
7	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**PRIX PHARMACEUTICA** 26 - ABBOT ROAD, LAHORE **(034401D)**
	Application Form Dy. No / Tracking ID & date of submission	(MP3-VWW-7QDB, 2025-10-18)
	Detail of Fee Submitted	75000, 238500 2025-10-16, 2025-12-04
	The proposed proprietary name / brand name	**BEL-LUMPY** **Live Lyophilized Vaccine against small pox of sheep, goats & infectious (nodular) dermatitis of cattle**
	Label Claim	Each dose (1ml) contains: Sheep & Goat: Live attenuated Sheep Capripoxvirus, PKPBA-V-411 strain.....not less than 3.0logTCD50 Cattle: Live attenuated Sheep Capripoxvirus, PKPBA-V-411 strain.....not less than 4.0logTCD50
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ML-De-Controlled
	Shelf Life (Unit)	18 Year(s)2°C - 8°C
	For generic drugs (me-too Status)	LUMPYVAC
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	M/s OJSC "BelVitunipharm"-211309, Vitebsk region, Vitebsk district, village Dolzha, Sovetskaya str., 26 A-Belarus
	Name, address of Marketing Authorization Holder:	M/s OJSC "BelVitunipharm", 211309, Vitebsk region, Vitebsk district, village Dolzha, Sovetskaya str., 26 A, Belarus
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	.
	Evaluation Remarks	
	EWG in its 12th meeting deliberated that Poxvirus vaccines provide species specific immunity and in applied vaccine, the Capripox virus used, is isolated from Sheep. Hence, the product is only be recommended for small pox of sheep and not recommended for small pox of goat & infectious nodular dermatitis of cattle.	
	Decision	
	Approved Keeping in view the recommendations of Expert Working Group (EWG); Registration Board approved the product for immunization against Sheep Pox disease only with change in brand name & Label claim as follows:	

	BEL-POX (Live Lyophilized Vaccine Against Small Pox of Sheep) Each dose (1ml) contains: Live attenuated Sheep Capripoxvirus, PKPBA-V-411 strain.....not less than 3.0logTCD50	
8	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**Kam Pharma** Upper Floor Property NoP-246Main Fatima Jinnah Road Millat Abad Sargodha **(08-384-0120-120589D)**
	Application Form Dy. No / Tracking ID & date of submission	(DJX-2MA-W3UZ, 2026-02-27)
	Detail of Fee Submitted	313500, 2026-02-23,
	The proposed proprietary name / brand name	**KEYIAN** **Newcastle Disease, Infectious Bronchitis and Egg Drop Syndrome Vaccine, Inactivated (Strain La Sota+Strain M41+Strain HSH23)**
	Label Claim	Each dose (0.5ml) contains: Inactivated Newcastle disease Strain LaSota.....≥ $10^{8.3>}EID_{50}$ Inactivated Infectious Bronchitis Strain M41.....≥$10^{6.3>}EID_{50}$ Inactivated Egg Drop Syndrome Strain HSH23.....≥1000 HAU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500ML (1000 Doses)-De-Controlled
	Shelf Life (Unit)	18 Month(s)2°C - 8°C
	For generic drugs (me-too Status)	Product Name:: ITA ND+IB+EDS Vaccine Registration No: 062005 Registration Date: 2010-01-07
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Wuhan Keqian Biology,.Co.Ltd-No 419, Gaoxin Second Road, East Lake High Tech Development Zone, Wuhan-China
	Name, address of Marketing Authorization Holder:	Wuhan Keqian Biology,.Co.Ltd, No 419, Gaoxin Second Road, East Lake High Tech Development Zone, Wuhan, China
	Details of Certificates (CoPP/FSC/cGMP):	GMP Certificate No. (2025)GMP 17002 dated 10-09-2025 valid till 09-09-2030.
	Details of Authorization Letter :	Apostille LOA dated 26-11-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	EWG in its 12th meeting recommended the product for grant of registration. Moreover, initially the firm applied for volume 500ml and then requested to change the volume to 250ml and submitted fee of Rs. 313500/-.	
	Decision	
	Approved Keeping in view recommendations of EWG and submitted GMP & FSC; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	

9	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**Hivet International** First Floor, Plaza#112-CCA, Block-A, KHAYABAN E AMIN Housing Society, Lahore. **(05-352-0066-127450D)**
	Application Form Dy. No / Tracking ID & date of submission	(PY1-2HN-64VM, 2026-04-01)
	Detail of Fee Submitted	313500, 2026-03-31,
	The proposed proprietary name / brand name	**SINVAC ND+H9+FADV** **Combined Newcastle Disease. Avian Influenza (subtype H9)and Avian Adenovirus Disease (Serotype 4, Group 1) Vaccine, Inactivated (Strain La Sota+ Strain SD95+ Strain SDC4)**
	Label Claim	Each 0.1 ml before inactivation contains: Newcastle disease virus, Strain La Sota.....$\geq 10^{8.5}EID_{50}$ Avian influenza virus subtype H9, Strain SD95.....$\geq 10^{7.5}EID_{50}$ Avian Adenovirus, Strain SDC4.....$\geq 10^{7.5}EID_{50}$
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500ml-De-Controlled
	Shelf Life (Unit)	18 Month(s)2 – 8 °C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Beijing Sinder-Vet Technology CO. LTD.-No. 118 Shunyu Road, Beijing Tianzhu Airport Economic Development Zone, Shunyi District, Beijing, China-China
	Name, address of Marketing Authorization Holder:	Beijing Sinder-Vet Technology CO. LTD., No. 118 Shunyu Road, Beijing Tianzhu Airport Economic Development Zone, Shunyi District, Beijing, China
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate No. (2021) GMP 01010 dated 29-11-2021 valid till 28-11-2026 FSC dated 15-08-2025.
	Details of Authorization Letter :	LOA dated 25-09-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	EWG in its 12th meeting recommended the product for grant of registration.	
	Decision	
	Approved Keeping in view recommendations of EWG and submitted GMP & FSC; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
10	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**Huzaifa International** commercial area, aziz bhatti town, Sargodha **(08-384-0120-022405D)**
	Application Form Dy. No / Tracking ID & date of submission	(JAB-GAD-3365, 2025-09-25)

	Detail of Fee Submitted	313500, 9400 2025-08-22, 2025-11-13
	The proposed proprietary name / brand name	**FELINE VAC-3**
	Label Claim	Each 1ml of Dose; Active agents; 1 Feline herpesvirus type 1 (Feline Rhinotracheitis) ≥10^2.5 TCID50 2 Feline Calicivirus ≥10^2.5 TCID50 3 Feline Panleukopenia virus ≥10^2.5 TCID50 Inactive ingredients: Lactalbumine 5% Sucrose 10% Thiomersal 1:10.000 (w/v) Penicillin G sodium 100 IU/dose Streptomycin sulfate 100 µg/dose Amphotericin B 25 µg/dose (Eu.Phr. spec.) Composition of Diluent: Sodium chloride (NaCl) 80 mg Potassium chloride (KCl) 2 mg Disodium phosphate (Na2HPO4*2H2O 11,5 mg Potassium hydrogen phosphate (KH2P04) 2 mg Distilled Water 1 ml (Innovator's spec.)
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1 Dose vaccine with 1 ml diluent-De-Controlled
	Shelf Life (Unit)	24 Month2~8 °C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	VETAL HAYVAN SAĞLIĞI (Vetal Animal Health Products-Organize Sanayi Bolgesi, Petrol Mah.14 cad. No.1, ADIYAMAN / TURKEY-Turkey
	Name, address of Marketing Authorization Holder:	VETAL HAYVAN SAĞLIĞI (Vetal Animal Health Products, Organize Sanayi Bolgesi, Petrol Mah.14 cad. No.1, ADIYAMAN / TURKEY, Turkey
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Keeping in view the recommendations of EWG; Registration Board in its 352nd meeting deferred the case for submission of following by the firm: "Safety and Efficacy data of applied product." The response of firm was considered in 12th meeting of EWG wherein following was decided: "EWG recommended the product for grant of registration."	
	Decision	
	Approved Keeping in view recommendations of EWG and submitted GMP & FSC; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
11	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**SAADAT INTERNATIONAL** 117-HABITAT APARTMENTS, SHADMAN-II, JAIL ROAD **(05-352-0063-102851d)**
	Application Form Dy. No / Tracking ID & date of submission	(24T-1TW-J9U7, 2026-03-02)
	Detail of Fee Submitted	313500, 2026-02-27,
	The proposed proprietary name / brand name	**GALLIMUNE H9**

	Label Claim	GALLIMUNE H9 vaccine is administered by parenteral route and induces an active immunization in broiler chickens and layer or breeder pullets against Avian Influenza (H9N2 subtype).
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1000ds/300ml-De-Controlled
	Shelf Life (Unit)	18 Month+2 to +8 C'
	For generic drugs (me-too Status)	Reg#126092 Gallimune H9ND
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Boehringer Ingelheim Animal Health Italia S.p.a-Via Baviera 9, 35027 Noventa Padovana, Italia/Italy-Italy
	Name, address of Marketing Authorization Holder:	Boehringer Ingelheim Vetmedica GmbH, Binger Strabe 173, 55216 Ingelheim am Rhein, , Germany
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	EWG in its 12th meeting decided to ask the firm to submit detailed studies regarding, history, origin, immunological relevance and need of Irak strain for Pakistan.	
	Decision	
	Deferred Keeping in view the recommendations of EWG; Registration Board deferred for submission of detailed studies regarding, history, origin, immunological relevance and need of Irak strain for Pakistan.	
12	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**MS Enterprises** P42/2, Opp Municipal Degree College, Jaranwala Road Fasialabad **(063310168118843D)**
	Application Form Dy. No / Tracking ID & date of submission	(BA7-R1J-DNB4, 2025-12-05)
	Detail of Fee Submitted	313500, 2025-11-26,
	The proposed proprietary name / brand name	**ADENOVIRUS ATV**
	Label Claim	Each dose of 0.5 mL of vaccine contains, as a minimum: ANTIGEN PHASE ..... mL Adenovirus I sv1 (FadV sv1) .....105.0 TCID50/DOSE Adenovirus I sv5 (FadV sv5) .....105.0 TCID50/DOSE Adenovirus I sv8 (FadV sv8) .....105.0 TCID50/DOSE Adenovirus I sv10 (FadV sv10) .....105.0 TCID50/DOSE Adenovirus I sv11 (FadV sv11) .....105.0 TCID50/DOSE Astrovirus (CastV) 106,0

		EID50/DOSE Excipient emulsion..... mL
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	The vial contains 500 ml, with 1000 doses -De-Controlled
	Shelf Life (Unit)	24 MonthThe product shout be kept at temperature 2°C at 8°C (35,6ºF at 46,4ºF) and protected from direct sunlight. Do not freeze.
	For generic drugs (me-too Status)	Product Name:: GPVAC Hydro-TC Plus Injection Registration No: 084594 Company Name: Grand Pharma Pvt Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Inata Produtos Biológicos Ltda.-Rodovia BR 365, Km 615 – Bloco D – Uberlândia - MG, ZIP Code: 38407-180-Brazil
	Name, address of Marketing Authorization Holder:	Inata Produtos Biológicos Ltda., Rodovia BR 365, Km 615 – Bloco D – Uberlândia - MG, ZIP Code: 38407-180, Brazil
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	EWG in its 12th meeting did not recommend the product for grant of registration as SV 5 & 10 have never been reported from Pakistan.	
	Decision	
	Rejected Keeping in view the recommendations of EWG; Registration Board did not acceded to request of firm for grant of registration as the product is containing serovars 5 & 10 while these have never been reported from Pakistan.	
13	Case Category	Import (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	(9X6-JVR-TS6L, 2025-09-02)
	Detail of Fee Submitted	313500.0, 2025-08-25,
	The proposed proprietary name / brand name	**QVAC H5 (R14)**
	Label Claim	Each vial contains Reassortant Avian Influenza Virus (Subtype H5N8), HA titer is 1:128 (equals to 7log2) before inactivation
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	500ml-De-Controlled
	Shelf Life (Unit)	24 Month2-8°C
	For generic drugs (me-too Status)	1. GPVAC Flu-5 Avian Influenza Serotype. 2. Inactivated AIV H5N8 (EID50 not less than 108/ml) and Hemagglutinating units not 128 HAU 3. Inactivated AIV H5N8 containing not less than 64 HAU and EID50 n
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Zhengzhou Bio-Pharmaceutical Factory of QYH Biotec-Southeast of the Cross of Jieshi Road & Qinghao Road, Guandu Town, Zongmu Country, Zhengzhou City, Henan Province, China-China
	Name, address of Marketing Authorization Holder:	Zhengzhou Bio-Pharmaceutical Factory of QYH Biotec, Southeast of the Cross of Jieshi Road & Qinghao Road, Guandu Town, Zongmu Country, Zhengzhou City, Henan 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	
	Keeping in view the recommendations of EWG; Registration Board in its 352nd meeting deferred the case for submission of following by the firm: "Need and Presence of H5N8 in Pakistan." The response was considered in 12th meeting of EWG wherein following was decided: "May be referred to M/o NFSR for their comments regarding need and prevalence of H5N8 in Pakistan."	
	Decision	
	Deferred Keeping in view the recommendations of EWG; Registration Board referred the application to M/o NFSR for their comments regarding need and prevalence of H5N8 in Pakistan.	
14	Case Category	Import (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	(NYB-QEP-3SP5, 2026-03-14)
	Detail of Fee Submitted	313500, 2026-03-04,
	The proposed proprietary name / brand name	**QVAC ILT** **Infectious Laryngotracheitis Vaccine, Live**
	Label Claim	Each dose of vaccine contains: Infectious Laryngotracheitis Virus K317 strain.....>$10^{2.7}EID_{50}$
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	10vials/box-De-Controlled
	Shelf Life (Unit)	24 Month(s)2-8°C
	For generic drugs (me-too Status)	1. HIPRAVIAR ILT 2. IZOVAC ILT 3. Medivac ILT 4. Nobilis ILT 5. Pro-vac ILT
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	QYH Nanjing Biotech Company Limited-No.35 Xiangfeng Road, Jiangning Sub-district, Jiangning District, Nanjing City-China
	Name, address of Marketing Authorization Holder:	QYH Biotech Company Ltd, Building No. 20, Part 11, ABP, No. 188 Southwest 4th Ring Road, Fengtai District, Beijing, P.R. China, China
	Details of Certificates (CoPP/FSC/cGMP):	GMP Certificate No. (2023) GMP 10011 dated 14-06-2023 valid till 29-03-2028.
	Details of Authorization Letter :	POA dated 12-01-2026.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	

	EWG in its 12th meeting recommended the product for grant of registration.	
	Decision	
	Approved Keeping in view recommendations of EWG and submitted GMP & FSC; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
15	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**Martin Dow Marker Limited** Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S, Razi Road, Shahrah-e-Faisal, Karachi **(0523)**
	Application Form Dy. No / Tracking ID & date of submission	(HAG-4MW-1HEV, 2026-05-08)
	Detail of Fee Submitted	313500, 2026-05-05,
	The proposed proprietary name / brand name	**AFTOVIS**
	Label Claim	Purified inactivated foot and mouth disease (FMD) virus containing following strains: O Manisa + O-3039 + A Iran 05 + A GVII-2015 + Asia1 Shamir + Sat2 Eri Each 3 mL (1 dose) of vaccine contains 6 or more PD50 per valency.
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled,200ml-De-Controlled,300ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year2°C - 8°C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Boehringer Ingelheim Animal Health France-Rue de l'Aviation 69800 Saint Priest – France-France
	Name, address of Marketing Authorization Holder:	Boehringer Ingelheim Vetmedica GmbH , Binger Straße 173, 55216 Ingelheim am Rhein, Germany, , Germany
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	EWG in its 12th meeting recommended to refer to M/o NFSR for their comments regarding need and prevalence of SAT-2 in Pakistan.	
	Decision	
	Deferred Keeping in view the recommendations of EWG; Registration Board referred the application to M/o NFSR for their comments regarding need and prevalence of applied strains of FMD virus in Pakistan.	
16	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**CLOUD AGRI PAKISTAN** 45-A2 JOHAR TOWN LAHORE **(2029-02)**
	Application Form Dy. No / Tracking ID & date of submission	(VZB-3ZZ-6ANM, 2025-05-25)

	Detail of Fee Submitted	300000.0, 2025-03-20,
	The proposed proprietary name / brand name	**Bioaftogen O+A+SAT2+Asia1**
	Label Claim	Not submitted.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	24 Month(s)Store and transport between 2˚C and 8˚C
	For generic drugs (me-too Status)	INOVATOR
	Pharmacotherapeutic Group of (API)	Veterinary Viral Vaccine
	Name, address of Manufacturing site:	BIOGÉNESIS BAGÓ S.A.-RUTA PANAMERICANA, 38.5 KM. (B16191EA) GARIN, BUENOUS AIRES, ARGENTINA.-Argentina
	Name, address of Marketing Authorization Holder:	BIOGENESIE BAGO, RUTA PANAMERICANA, 38.5 KM. (B16191EA) GARIN, BUENOUS AIRES, ARGENTINA., Argentina
	Details of Certificates (CoPP/FSC/cGMP):	FSC provided mentions that the product is registered for export Valid GMP certificate of manufacturer has been submitted.
	Details of Authorization Letter :	Not Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Not submitted
	Evaluation Remarks	
	EWG in its 12th meeting recommended to refer to M/o NFSR for their comments regarding need and prevalence of SAT-2 in Pakistan.	
	Decision	
	Deferred Keeping in view the recommendations of EWG; Registration Board referred the application to M/o NFSR for their comments regarding need and prevalence of applied strains of FMD virus in Pakistan.	
17	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**MS Enterprises** P42/2, Opp Municipal Degree College, Jaranwala Road Fasialabad **(063310168118843D)**
	Application Form Dy. No / Tracking ID & date of submission	(4EV-PQN-1E3Q, 2026-01-15)
	Detail of Fee Submitted	313500, 2025-12-23,
	The proposed proprietary name / brand name	**Premvac H9ND Ultra**
	Label Claim	Each 0.2ml of dose contains: Avian Influenza Viruses (AIV), Strains A/ chicken/ Egypt/FAO-S33/2021 (H9N2) 10 8.5 EID50 before inactivation H9N2 antigen >512 HAU*/dose after inactivation 2- NDVGII (Egypt /NDV/VIRO1-Lasota/RLQP/2021) 10 8.5 EID50 before inactivation NDVGII antigen >512 HAU/Dose after inactivation
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500ML Bottle-De-Controlled

	Shelf Life (Unit)	24 MonthThe vaccine must be stored at 2°C - 8°C, do not freeze the vaccine
	For generic drugs (me-too Status)	Product Name:: AI-OLVAC H9 Registration No: 077561 Company Name: Forward Solutions
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Eva pharma for pharmaceutical industries (Eva phar-Plot 27. Polaris International Park, North expansion of 1st Industrial Zone, 6th October City Giza-Egypt
	Name, address of Marketing Authorization Holder:	Eva pharma for pharmaceutical industries (Eva phar, Plot 27. Polaris International Park, North expansion of 1st Industrial Zone, 6th October City Giza, Egypt
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	EWG in its 12th meeting decided to ask the firm to submit detailed studies regarding, history, origin, immunological relevance and need of applied strains of both viruses for Pakistan.	
	Decision	
	Deferred Keeping in view the recommendations of EWG; Registration Board deferred for submission of detailed studies regarding, history, origin, immunological relevance and need of applied strains for Pakistan.	
18	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**HIPHARMA (PRIVATE) LIMITED** 123-C (FIRST FLOOR), BLOCK E, MODEL TOWN LAHORE **(05-352-0065-127168D)**
	Application Form Dy. No / Tracking ID & date of submission	(PVY-ZS5-35X7, 2026-04-11)
	Detail of Fee Submitted	313500, 9400 2026-04-10, 2026-08-03
	The proposed proprietary name / brand name	**Hivac ND-IB (Multi) - EDS** **Newcastle Disease, Infectious Bronchitis and Egg Drop Syndrom Vaccine, Inactivated**
	Label Claim	Each 0.1ml before inactivation contains: Newcastle Disease virus, strain La Sota G2/G7.....$\geq 10^{8.5}EID_{50}$ Infectious Bronchitis virus, strain (M41+QX).....$\geq 10^{7.0}EID_{50}$ Egg Drop Syndrome virus, strain EDS 76.....$\geq 10^{7.0}TCID_{50}$
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	The 500 ml/bottle presentation is requested for registration.-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store between 2-8°C. Protect from light. Do not freeze
	For generic drugs (me-too Status)	Jova Zeit 1,2,4 (Reg No. 111181)
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine

	Name, address of Manufacturing site:	Qixiang Biological Technology Co., Ltd-Heshuo Road 5-333 Wuzhi, Henan , China.-China
	Name, address of Marketing Authorization Holder:	Qixiang Biological Technology Co., Ltd, Heshuo Road 5-333 Wuzhi, Henan , China., China
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate No. (2022) GMP 16016 dated 31-03-2022 valid till 30-03-2027. FSC dated 26-03-2026.
	Details of Authorization Letter :	Apostille Agreement dated 25-02-2026.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	EWG in its 12th meeting decided to ask the firm to submit detailed studies regarding, history, origin, immunological relevance and need of La Sota G2/G7 & IBV QX strain for Pakistan.	
	Decision	
	Deferred Keeping in view the recommendations of EWG; Registration Board deferred for submission of detailed studies regarding, history, origin, immunological relevance and need of applied strains for Pakistan.	
19	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**VET PHARMA TRADING CO** NEW STEEL MARKET, G.T. ROAD GUJRANWALA **(09-341-0137-069656D)**
	Application Form Dy. No / Tracking ID & date of submission	(JBN-JUL-A5S9, 2026-02-28)
	Detail of Fee Submitted	313500, 2026-02-24,
	The proposed proprietary name / brand name	**Himmvac Dalguban Adeno Plus Oil Vaccine**
	Label Claim	Each one dose contains: Inactivated Fowl Adenovirus type 4, K531/07 strain ..... at least $10^{7.0}TCID_{50}$ Inactivated Fowl Adenovirus type 8b, K194/19 strain..... at least $10^{7.0}TCID_{50}$
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,000 Dose (500 ml)-De-Controlled
	Shelf Life (Unit)	24 Year(s)(2-8°C)
	For generic drugs (me-too Status)	yes
	Pharmacotherapeutic Group of (API)	.
	Name, address of Manufacturing site:	M/s KBNP, INC.,-235-9, Chusaro, Sinam, Yesan, Chungnam, Republic of Korea.-South Korea
	Name, address of Marketing Authorization Holder:	Vet Pharma Trading Company,, New Steel Market, Near Regent Cinema, G.T. Road, Gujrawala., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	.
	Details of Authorization Letter :	.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	.
	Evaluation Remarks	
	EWG in its 12th meeting decided to ask the firm to submit detailed studies regarding, history, origin, immunological relevance and need of applied strains of both viruses for Pakistan.	
	Decision	

	Deferred Keeping in view the recommendations of EWG; Registration Board deferred for submission of detailed studies regarding, history, origin, immunological relevance and need of applied strains of both viruses for Pakistan.	
20	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**HIPHARMA (PRIVATE) LIMITED** 123-C (FIRST FLOOR), BLOCK E, MODEL TOWN LAHORE **(05-352-0065-127168D)**
	Application Form Dy. No / Tracking ID & date of submission	(A13-TED-BRNP, 2026-04-17)
	Detail of Fee Submitted	313500, 2026-04-16,
	The proposed proprietary name / brand name	**Hivac Coryza** **nfectious Coryza (Serotype A+B+C) Vaccine, Inactivated**
	Label Claim	Each ml contains: Inactivated Avibacterium paragallinarum type A strain IC01.....$\geq 10^{10}$CFU Inactivated Avibacterium paragallinarum type B strain IC02.....$\geq 10^{10}$CFU Inactivated Avibacterium paragallinarum type C strain IC03.....$\geq 10^{10}$CFU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	The 500 ml/bottle presentation is requested for registration.-De-Controlled
	Shelf Life (Unit)	24 Month(s)Store between 2-8°C. Protect from light. Do not freeze
	For generic drugs (me-too Status)	Nobilis Coryza (Reg. No. 012884)
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Qixiang Biological Technology Co., Ltd-Heshuo Road 5-333 Wuzhi, Henan , China.-China
	Name, address of Marketing Authorization Holder:	Qixiang Biological Technology Co., Ltd, Heshuo Road 5-333 Wuzhi, Henan , China., China
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate No. (2022) GMP 16016 dated 31-03-2022 valid till 30-03-2027. FSC dated 26-03-2026.
	Details of Authorization Letter :	Apostille Agreement dated 25-02-2026.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	EWG in its 12th meeting decided to ask the firm to submit detailed studies regarding, history, origin, immunological relevance and need of applied strains for Pakistan.	
	Decision	
	Deferred Keeping in view the recommendations of EWG; Registration Board deferred for submission of detailed studies regarding, history, origin, immunological relevance and need of applied strains of both viruses for Pakistan.	
21	Case Category	Import (M. Zubair Masood)

	Name, address of Applicant.	**Martin Dow Marker Limited** Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S, Razi Road, Shahrah-e-Faisal, Karachi **(0523)**
	Application Form Dy. No / Tracking ID & date of submission	(W35-H62-XWUR, 2026-05-07)
	Detail of Fee Submitted	313500, 2026-05-05,
	The proposed proprietary name / brand name	**Bovela** **Lyophilisate and solvent for suspension for Injection**
	Label Claim	Each dose (2 mL) of the Lyophilisate vaccine contains: Modified live BVDV-1, non-cytopathic parent strain KE-9.....$10^{4.0}$-$10^{6.0}$$TCID_{50}$ Modified live BVDV-2, non-cytopathic parent strain NY-93.....$10^{4.0}$-$10^{6.0}$$TCID_{50}$ Solvent: Each 2ml contains: Sodium Chloride.....16.0mg Potassium Chloride.....0.4mg Potassium dihydrogen phosphate.....0.4mg Disodium hydrogen phosphate.....2.3mg Water for Injection.....q.s. 2ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)2°C-8°C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Boehringer Ingelheim Animal Health USA Inc-2621 North Belt Highway, St. Joseph, Missouri, 64506-2002 – USA-United States of America
	Name, address of Marketing Authorization Holder:	Boehringer Ingelheim Vetmedica GmbH , Binger Straße 173, 55216 Ingelheim am Rhein, Germany, , Germany
	Details of Certificates (CoPP/FSC/cGMP):	EMA CoPP No. 01/26/003734 dated 07-04-2026
	Details of Authorization Letter :	LOA dated 17-12-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	EWG in its 12th meeting recommended to refer to M/o NFSR for their comments regarding need and prevalence of BVD and its strains in Pakistan.	
	Decision	
	Deferred Keeping in view the recommendations of EWG; Registration Board referred the application to M/o NFSR for their comments regarding need and prevalence of need and prevalence of BVD and its strains in Pakistan	
22	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**tec man international** Plot # 276, Bhangril Road, 0.5 Km, T Chowk,Rawat **(DHO-ISB-2642)**

	Application Form Dy. No / Tracking ID & date of submission	(BA1-EAM-P1GQ, 2025-01-14)
	Detail of Fee Submitted	225000.0, 2024-11-14,
	The proposed proprietary name / brand name	**PRIMUN GUMBORO**
	Label Claim	Each dose contains: Live attenuated infectious bursal disease (IBD) virus, intermediate IBDV-IGS.....3.0-4.5 log10EID50
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1000 Doses-De-Controlled
	Shelf Life (Unit)	24 Month(s)(2ºC – 8ºC)
	For generic drugs (me-too Status)	Not registered
	Pharmacotherapeutic Group of (API)	Live Viral Veterinary Vaccine
	Name, address of Manufacturing site:	LABORATORIOS CALIER, S.A.-Pol. Ind. De Leon. Ed. CEEI - Onzonilla (Leon) - 24231 – Spain-Spain
	Name, address of Marketing Authorization Holder:	LABORATORIOS CALIER, S.A., c/. Barcelones, 26. Les Franqueses del Valles (Barcelona), Spain, Spain
	Details of Certificates (CoPP/FSC/cGMP):	Legalized FSC dated 12-05-2022. Apostille Eudra GMP No. 087604/25/01 against inspection dated 25-10-2024.
	Details of Authorization Letter :	Apostille LOA dated 29-08-2025 valid for 03 years.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	EWG in its 12th meeting decided to ask the firm to submit detailed studies regarding, history, origin, immunological relevance and need of IBDV-IGS for Pakistan.	
	Decision	
	Deferred Keeping in view the recommendations of EWG; Registration Board deferred for submission of detailed studies regarding, history, origin, immunological relevance and need of IBDV-IGS for Pakistan.	
23	Case Category	Import (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	(T38-3N3-5U9G, 2025-09-15)
	Detail of Fee Submitted	313500, 9400 2025-09-02, 2025-11-06
	The proposed proprietary name / brand name	**Medivac ND B-EDS-IB T 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 MD54 strain (MD54 strain identical to Genotype VII.2 group).....at least $10^{7.0}EID_{50}$

		Inactivated Adenovirus 127 virus, Mc Ferran strain.....at least 1000 HA unit - Inactivated Infectious Bronchitis (IB) virus of Massachusetts 41.....at least $10^{4.5}EID_{50}$ Inactivated Infectious Bronchitis (IB) virus of (M01 strain (M01 strain identical to Genotype G1-19 or QX-like group).....at least $10^{4.5}EID_{50}$ Inactivated Infectious Bronchitis (IB) virus of M02 strain (M02 strain identical to Genotype G1-13 or 793B group).....at least $10^{4.5}EID_{50}$
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500 ml-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)	IZOVAC ND (Ghazi Brothers), GPVAC ND Kaseef (Grand Pharma), Avisan Multi (HIPRA), Olvac A+B (FATRO)
	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, JI. 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	
	Keeping in view the recommendations of Expert Working Group on Veterinary Drugs; Registration board in its 357th meeting deferred the case for submission of detailed studies of MD54, M01 & M02 strains regarding their similarity to existing strains of Pakistan. The response of the firm was discussed in 12th meeting of EWG wherein following was decided: "EWG did not recommend the product for grant of registration as firm could not establish genetic and antigenic similarity of MD54, MD M01 & M02 strains with existing strains of Pakistan."	
	Decision	
	Rejected Keeping in view the recommendations of EWG; Registration Board did not acceded to request of firm for grant of registration as firm could not establish genetic and antigenic similarity of MD54, MD M01 & M02 strains with existing strains of Pakistan.	
24	Case Category	Import (M. Zubair Masood)
	Name, address of Applicant.	**Hivet International** First Floor, Plaza#112-CCA, Block-A, KHAYABAN E AMIN Housing Society, Lahore. **(05-352-0066-127450D)**

	Application Form Dy. No / Tracking ID & date of submission	(GBU-N2J-2RE1, 2026-04-01)
	Detail of Fee Submitted	313500, 2026-03-31,
	The proposed proprietary name / brand name	**SINVAC ND+H9+IBD+FADV**
	Label Claim	Each 0.1 ml contains: Inactivated Newcastle disease virus (Strain La Sota) Pre-inactivation virus content ..... ≥ 10^(8.7) EID50 Inactivated Avian influenza (subtype H9) virus (Strain SD95) Pre-inactivation virus content ..... ≥ 10^(7.7) EID50 Infectious Bursal Disease (Proteinum VP2) Pre-inactivation agar diffusion titer ..... ≥ 1 : 64 Inactivated Avian Adenovirus (Strain SDC4) Pre-inactivation virus content ..... ≥ 10^(7.7) TCID50
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500ml-De-Controlled
	Shelf Life (Unit)	24 Month2 – 8 °C
	For generic drugs (me-too Status)	SINVAC ND+H9, Registration No. 101424
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Beijing Sinder-Vet Technology CO. LTD.-No. 118 Shunyu Road, Beijing Tianzhu Airport Economic Development Zone, Shunyi District, Beijing, China-China
	Name, address of Marketing Authorization Holder:	Beijing Sinder-Vet Technology CO. LTD., No. 118 Shunyu Road, Beijing Tianzhu Airport Economic Development Zone, Shunyi District, Beijing, China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	EWG in its 12th meeting recommended the product for grant of registration.	
	Decision	
	Approved Keeping in view recommendations of EWG and submitted GMP & FSC; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
25	Case Category	Import (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	(XJV-7JY-1Y2U, 2025-12-15)
	Detail of Fee Submitted	313500, 2025-12-11,
	The proposed proprietary name / brand name	**RINVAC ND+AI+FAD**
	Label Claim	Each 0.1ml contains: Inactivated Newcastle disease virus, strain La Sota.....$10^{9.0}EID_{50}$ before inactivation Inactivated Avian influenza virus (subtype H9) strain TJ-4.....$10^{9.0}EID_{50}$ before

	inactivation Inactivated Fowl adenoviruses (Serotype 4 Group I) strain RP-8-C.....$10^{7.5}TCID_{50}$ before inactivation
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	500ml/Bottle-De-Controlled
Shelf Life (Unit)	24 Year(s)Store at 2°C - 8°C
For generic drugs (me-too Status)	Same Strains already registered in Pakistan
Pharmacotherapeutic Group of (API)	Veterinary Vaccine
Name, address of Manufacturing site:	Tianjin Ringpu Bio-technology Co., Ltd., Airport E-No. 168, Huanhe South Road, Airport Economic Zone, Tianjin-China
Name, address of Marketing Authorization Holder:	Tianjin Ringpu Bio-Technology Co., Ltd., No. 1 Dongjiu Road, Tianjin Free Trade Area (Airport Economic Area), Tianjin, China
Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille GMP Certificate No. (2022) GMP 02002 dated 25-07-2025 valid till 13-01-2027. Scanned Apostille FSC No. 2025041 dated 18-11-2025.
Details of Authorization Letter :	Scanned Apostille Product Specific LOA valid till 03-11-2025.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
Evaluation Remarks	
The N subtype of Avian Influenza virus was not mentioned in label claim. The firm was asked for clarification and they submitted that there is N2 in their composition. Registration Board in its 360th meeting deferred the case for submission of immunological relevance and need of AIV TJ-4 strain and FAD RP-8-C strain for Pakistan. The response was considered in 12th meeting of EWG wherein following was decided: "EWG recommended the product for grant of registration."	
Decision	
Approved Keeping in view recommendations of EWG and submitted GMP & FSC; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	

Case No. 1: Minutes of 12th meeting of Expert Working Group on Veterinary Drugs.

Sr. No.	Name of Importer & Manufacturer	Brand Name & Composition	Pack Size, Shelf Life & Storage Conditions	Recommendations of EWG in its 12th meeting	Decision of RB
1.	Importer: M/s Brand Station, 69 Wocland villas Lahore, Near Raiwind Road, Lahore. Manufacturer: Yebio Bioengineering Co., Ltd., No. 260 Heyuan Road, Economy Zone of Hongdao, Qingdao, China.	Yeflu H5 + H7 V3 Each dose (0.5ml) contains: Before inactivation, the HA titer of the chicken embryo fluids of H5 subtype Re-11 and Re-12 strains, and H7 subtype H7-Re3 strain are all ≥1:512.	500ml 24 Months (2-8°C)	May be referred to M/o NFSR for their comments regarding need and prevalence of H5 and H7 in Pakistan.	**Keeping in view the recommendations of EWG; Registration Board referred the application to M/o NFSR for their comments regarding need and prevalence of H5 and H7 in Pakistan.**
2.	Importer: Forward Solutions, Plot No. 19-B, Qazalbash Chowk, Abdul Sattar Edhi Road, District Lahore Manufcturer: M/s Fatro S.p.A, Via Molino Emili, 2 – 25030 Maclodio (BS) – Italy.	G-OLVAC (Inactivated Oil Emulsified Vaccine) Each dose contains; Inactivated Newcastle Disease virus (La-Sota): not less than 108.5 EID50. Inactivated infectious bursal Disease virus (NEV 39): not less than 105.5 EID50	500ml 18 Months (2-8°C)	EWG decided to ask the firm to submit detailed studies regarding, history, origin, immunological relevance and need of NEV 39 strain for Pakistan.	**Keeping in view the recommendations of EWG; Registration Board deferred for submission of detailed studies regarding, history, origin, immunological relevance and need of NEV 39 strain for Pakistan.**
3.	Importer: M/s Ghazi Brothers Karachi. Importer: M/s IZO S.P.A Via A. Binachi Italy	Izovac CHB Freeze-dried live vaccine Each dose of vaccine contains:- Live attenuated Newcastle Disease Virus Strain Clone…..106 EID50 Live Attenuated Infectious Bronchitis Strain Massachusetts H120……103EID5 0 Live Attenuated Infectious Bronchitis Strain 28/86…..103EID50	1000 & 2500 doses 24 months	EWG did not recommend the product for grant of registration as firm could not establish genetic and antigenic similarity of 28/86 strain with existing strains of Pakistan.	**Keeping in view the recommendations of EWG; Registration Board did not acceded to request of firm for grant of registration as firm could not establish genetic and antigenic similarity of 28/86 strain with existing strains of Pakistan.**
4.	Importer: M/s Ghazi Brothers Karachi.	IZOVAC NDFLU (Emulsified Inactivated Vaccine against Newcastle	50 doses	May be referred to M/o NFSR for their comments	**Keeping in view the recommendations of EWG; Registration**

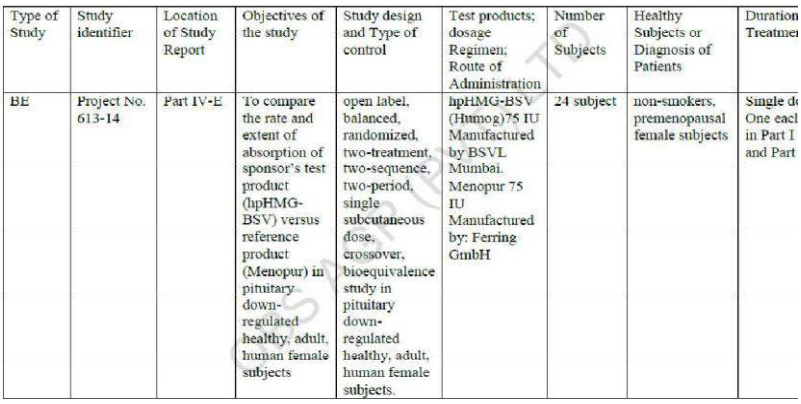
	Importer: M/s IZO S.P.A Via A. Binachi Italy	Disease and Avian influenza A) Each dose of 0.5 ml of vaccine contains: Inactivated Newcastle Disease Virus……50 PD50 Inactivated whole avian influenza virus antigen f H5-N9 subtype strain A/ck/lt/22A/98: HI.=6 Log2 in oil Emulsion		regarding need and prevalence of H5 in Pakistan.	**Board referred the application to M/o NFSR for their comments regarding need and prevalence of H5 in Pakistan.**
5.	Importer: M/s Huzaifa International, Commercial area, Aziz Bhatti Town, Sargodha. Manufacturer: M/s Komipharm International Co. Ltd. 17, Gyeongje-ro, Siheung-Si, Gyeonggi-do, South Korea.	PRO-VAC H5-AINK Inactivated poultry vaccine Each 0.5mL contains: HA Recombinant antigen of H5 type highly pathogenic Avian Influenza virus [(H5N1), (H5N6) derived HA protein]…≥ 29.0 HA Unit Newcastle Disease virus (Ulster 2C strain), before inactivation…≥ $10^{8.5}EID_{50}$	500ml 24 Months (2-8°C)	May be referred to M/o NFSR for their comments regarding need and prevalence of H5N1 & H5N6 in Pakistan.	**Keeping in view the recommendations of EWG; Registration Board referred the application to M/o NFSR for their comments regarding need and prevalence of H5N1 & H5N6 in Pakistan.**
6.	M/s Hivet Animal Health Business, 1st Floor,667-P. MA, Johar Town, Lahore, Pakistan Sanfer Salud Animal S.S. de C.V. Boulevard Adolfo Lopez Mateos 314-PB, Colonia Tlaco[ac, ALVARO Obregon C.P.0049 Ciudad de Mexico.	Genovax N5 Each ml contains; Attenuated ND virus Genotype V strain rP05…..minimum 107.5 DIEP50	1000, 2500 & 10000 doses 18 Months (2-4°C)	EWG did not recommend the product for grant of registration as firm could not submit sufficient evidence to establish genetic and antigenic similarity of Genotype V with existing strains of Pakistan.	**Keeping in view the recommendations of EWG; Registration Board did not acceded to request of firm for grant of registration as firm could not establish genetic and antigenic similarity of Genotype V with existing strains of Pakistan.**

Rest of the cases were of E-App, hence, included in additional agenda through E-App.

Case#02: Imported human biological applied by M/s OBS AGP Limited deferred in 353rd 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,2nd 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)	Original, Legalized and valid CoPP 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	Original, Legalized and Valid Letter of Authorization 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 ± 2°C / 60 ± 5%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  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.

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 Treatmer
BE	Project No. 613-14	Part IV-E	To compare the rate and extent of absorption of sponsor's test product (hpHMG-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.	hpHMG-BSV (Humog)75 IU Manufactured by BSVL Mumbai. Menopur 75 IU Manufactured by: Ferring GmbH	24 subject	non-smokers, premenopausal female subjects	Single d One eacl in Part I and Part

		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

The Registration Board deferred the case for the submission of above cited documents.

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.	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

	Clarification/justification is required.		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	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	-

	chloride. Clarification is required	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** Marketing Authorisation Holder: Ferring Pharmaceuticals Ltd. Drayton Hall, Church Road, West Drayton, UB7 7PS, UK PL 03194/0109 Manufacturer: Ferring GmbH Wittland 11, D-24109 Kiel, Germany Reference attached as ***Annexure 9.***	**Submitted**

Concluding remarks:

- 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.

Decision of 351st meeting:

Registration Board deferred the case for submission of following documents/ clarifications;

i. *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.*
ii. *In-use stability data is required.*
iii. *Detail of the laboratory where characterization was performed and results of characterization is required.*

Evaluation by BE&R:

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 of 353rd meeting:
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.*

Evaluation by BE&R:

The firm submitted a reply as under;
"We acknowledge Ministry's remarks and would like to confirm that BSV has not performed any Phase-3 clinical studies based on below rationale –
Rationale for absence of Phase III data:
Menotropin is an established drug that has been approved for decades, so Phase 3 studies are not typically needed for its currently approved indications. The guidelines allow for approval without Phase 3 trials,

- It is an approved, established drug: Menotropins were introduced into clinical use in 1961 and various formulations (e.g., Menopur) have been approved by regulatory bodies like the FDA and EU authorities.
- Generic formulations: BSV are the generic version of an already approved menotropin product, hence Phase 3 efficacy trial is not required if bioequivalence to the approved reference product is demonstrated through pharmacokinetic (PK) studies (refer Project No. 613-14 Annexure 1).
- Post-market requirements: BSV Humog being the legacy product it is been marketed over extent of period where no adverse effect events were reported. A latest PBRER has been included as Annexure-2 for reference. Hence, this proves the safety and efficacy of BSV Humog over decades.
- A Human Pharmacokinetic similarity study of applied product with the Reference product remains the strong rationale for Phase-III waiver of biologics.
- The product is approved in PIC/S member countries, including Malaysia, Philippines and Ukraine, which follow stringent international regulatory standards.

Conclusion:
Since the applied product meets the required quality standards based on CMC compliance and safety data, and the PK/PD results from the Phase I study demonstrate that there is no further requirement for Phase III studies, this position is consistent with regulatory requirements guidelines of (e.g., USFDA). The guidance supporting the Phase III waiver is provided in Annexure-3.
As per newly emerging guidance's to avoid unnecessary exposure to patients and for cost effectiveness it is recommended not to perform entire study if not required.

Decision of 361st meeting:
Registration Board decided to defer the case for submission of clinical trial data of applied product.

Case#03: Imported human biological applied by M/s Himmel Pharmaceuticals (Pvt.) Ltd., Lahore considered in 334th meeting.

Following product of M/s Himmel Pharmaceuticals (Pvt.) Ltd., Lahore was considered in 334th meeting of Rgeistration Board wherein the Board decided as follows:

Name of Manufacturer	Brand Name & Composition	Pack Size & Shelf Life	Decision of RB

M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular Road, Motijheel Dhaka, Bangladesh	Pembroxim Injection 100mg Each 4 ml contains Pembrolizumab INN……..100mg	1's 24 months (2-8^{0}C)	Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit the differential fee before issuance of registration letter.

Later on, it was noted that Biosimilarity data provided in initial application was of bulk manufacturer, hence, as per requirement, the firm was asked to submit Biosimilarity data of finished product manufactured by finished product manufacturer vide letter No. F. 3-12/2021-AD(BD)(Vol-I)(M-351) dated 17-10-2025. The firm has submitted the data which is under evaluation.

Decision:

Keeping in view the discussions regarding Pembrolizumab containing local and imported formulations; Registration Board decided that Product specific inspection, shall be conducted by following panel of experts:

i. **Two evaluators from Division of Biological Evaluation & Research, DRAP.**
ii. **Dr. Ali Jan, Director Drug Testing Laboratory, Quetta.**
iii. **Mr. Syed Adnan Rizvi, Director Drug Testing Laboratory, Karachi.**
iv. **Mr. Asad Abrar, Director Drug Testing Laboratory, Bahawalpur.**

Meeting ended with vote of thanks to and for the Chair.

-------End of Document------