

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
570	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Kanel Pharma Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat (000758)
	Application Form Dy. No / Tracking ID & date of submission	(PYT-HNP-XU2M, 2026-03-31)
	Detail of Fee Submitted	97200.0, 2025-09-01,
	The proposed proprietary name / brand name	METHROL 1GM INJECTION
	Label Claim	Each vial contains:- Methylprednisolone Sodium Succinate 1gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year Controlled Room Temperature
	For generic drugs (me-too Status)	SOLU MEDROL INJECTION By Pfizer
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	M/S Wenovo Pharmaceuticals-Plot # 31,32, Punjab Small Industrial Estate, Taxila, Rawalpindi -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Methyl 1gm Injection, Meeting 339th
	Evaluation Remarks	
571	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Saaaf Pharmaceuticals Risalpur, Nowshera, Khyber Pakhtunkhwa 23200 (000637)
	Application Form Dy. No / Tracking ID & date of submission	(LJY-16Y-2HDH, 2026-02-09)
	Detail of Fee Submitted	97200, 2025-11-17,
	The proposed proprietary name / brand name	Esoprox
	Label Claim	Each Modified release tablets contains:- Naproxen 500mg (as Enteric coated) ESOMEPRAZOLE AS MAGNESIUM TRIHYDRATE.....20MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28"s-As per SRO
	Shelf Life (Unit)	2 Year Below 25 c

	For generic drugs (me-too Status)	yes
	Pharmacotherapeutic Group of (API)	Yes
	Name, address of Manufacturing site:	M/s Medizan Laboratories (Pvt)Ltd-Plot no. 313, Industrail triangle kahuta road, Islamabad-
	The status in reference regulatory authorities	Yes
	Detail of previous approval	Esik 500mg/20mg MR Tablets
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 24 October 2025 vide application TID: MD5-JST-R8LA.	
	Decision	
	Approved	
572	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Saaaf Pharmaceuticals Risalpur, Nowshera, Khyber Pakhtunkhwa 23200 (000637)
	Application Form Dy. No / Tracking ID & date of submission	(4T2-GRA-9BD3, 2026-02-23)
	Detail of Fee Submitted	97200, 2025-11-17,
	The proposed proprietary name / brand name	Iro-P
	Label Claim	Iron as Ferric Carboxymaltose.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10mlx01's & 10mlx05's-As per SRO
	Shelf Life (Unit)	2 YearBelow 25 c
	For generic drugs (me-too Status)	yes
	Pharmacotherapeutic Group of (API)	Yes
	Name, address of Manufacturing site:	M/s Bio-Labs (Pvt.) Ltd.-located at Plot No. 145, Industrial Triangle Kahuta Road Islamabad-
	The status in reference regulatory authorities	Yes
	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. The cross-referred product was approved in PRV dated 05-December 2025 vide application TID: PGB-UUG-GSES.	
	Decision	
	Approved	
573	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	(LMT-TN5-1SXW, 2025-11-03)
	Detail of Fee Submitted	97200, 2025-10-29,
	The proposed proprietary name / brand name	Kaloprid-2MG TABLET
	Label Claim	Each film coated tablet contains Prucalopride Succinate eq. to Prucalopride.....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 Year30C
	For generic drugs (me-too Status)	Me To Registration Status: Registered in Pakistan Brand Name: Prulevity 2mg Tablet Manufacture: Ferozsans Laborataries Ltd.. Address: P.O.Ferozsans, Amangarh - Nowshera(Khyber Pakhtunkhwa)
	Pharmacotherapeutic Group of (API)	Dihydro-benzofuran-carboxamide WHO ATC Code: A06AX05
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	SRA Registration Status: USFDA Approved New Drug Application (ANDA): 218492 Brand Name: Prucalopride Succinate 2mg tablets
	Detail of previous approval	PRVC(SVW-2L1-MBUP)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 03 June 2025 vide application TID: SVW-2L1-MBUP.	
	Decision	
	Approved	
574	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	(URR-YWL-6ZA9, 2025-11-03)
	Detail of Fee Submitted	97200, 2025-10-29,
	The proposed proprietary name / brand name	Kaloprid-1MG TABLET
	Label Claim	Each film coated tablet contains Prucalopride Succinate eq. to Prucalopride.....1mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO

	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Me To Registration Status: Registered in Pakistan Brand Name: Prulevity 1mg Tablet Manufacturer: Ferozsans Laboratrics Ltd. Address: : P.O.Ferozsans, Amangarh - Nowshera(Khyber Pakhtunkhwa)
	Pharmacotherapeutic Group of (API)	Dihydrobenzofuran-carboxamide derivative. WHO ATC Code: A06AX05
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	SRA Registration Status: USFDA Approved New Drug Application (ANDA): 218492 Brand Name: Prucalopride Succinate 1mg tablets Novitium
	Detail of previous approval	55D-ZUG-8Q6Z(PRVC)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 03-June 2025 vide application TID: 55D-ZUG-8Q6Z.	
	Decision	
	Approved	
575	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	RELIZON PHARMACEUTICALS PLOT NO 118 SUNDAR INDUSTRIAL ESTATE RAIWIND ROAD LAHORE (000875)
	Application Form Dy. No / Tracking ID & date of submission	(LTP-DU6-HYQU, 2025-10-31)
	Detail of Fee Submitted	93000.0, 4200 2025-07-07, 2025-10-03
	The proposed proprietary name / brand name	Xontrix 500mg IM Injection
	Label Claim	Each Vial contains: Ceftriaxone Sodium eq. to Ceftriaxone 500mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Safe -One Injection 500mg by Shrooq pharmaceuticals Pvt. Ltd
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	Synchro Pharmaceuticals-77-Industrial Estate, Kot Lakhpat, Lahore.-
	The status in reference regulatory authorities	Rocephin Injection 500mg IM Injection F.Hoffman-La Roche Ltd. Switzerland USFDA Approved
	Detail of previous approval	Triomor 500mg IM Injection Approved in Post Registration Variation Committee in its 130th meeting of
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 16-September 2024.	
	Decision	
	Approved	
576	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	RELIZON PHARMACEUTICALS PLOT NO 118 SUNDAR INDUSTRIAL ESTATE RAIWIND ROAD LAHORE (000875)
	Application Form Dy. No / Tracking ID & date of submission	(SZM-V5B-6M3V, 2025-10-23)
	Detail of Fee Submitted	93000.0, 4200 2025-07-07, 2025-10-03
	The proposed proprietary name / brand name	Xontrix 250mg IM Injection
	Label Claim	Each Vial contains: Ceftriaxone Sodium eq. to Ceftriaxone 250mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Ceftriaxone For Injection 250mg by Mehran International karachi
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	Synchro Pharmaceuticals-77-Industrial Estate, Kot Lakhpat, Lahore.-
	The status in reference regulatory authorities	Rocephin Injection 250mg IM Injection F.Hoffman-La Roche Ltd. Switzerland USFDA Approved
	Detail of previous approval	Triomor 250mg IM Injection Approved in Post Registration Variation Committee in its 130th meeting of
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 16-September 2024.	
	Decision	
	Approved	
577	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	FESTEL LABORATORIES THOKAR NIAZ BAIG , MULTAN ROAD, LAHORE. (000556)

	Application Form Dy. No / Tracking ID & date of submission	(M7P-ZRE-NXMA, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	CEFEST 500mg INJECTION IM
	Label Claim	Each Vial contains: Ceftriaxone as sodium.....500mg
	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)	Esticef Injection 500mg by M/s Aulton Pharmaceutical, Hattar
	Pharmacotherapeutic Group of (API)	Data Already Approved in PRVC meeting , Please see attached.
	Name, address of Manufacturing site:	Nicholas Pharmaceuticals.-Plot # 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad-
	The status in reference regulatory authorities	Rocephin 500mg Powder for Solution for Injection or Infusion, MHRA UK
	Detail of previous approval	Magxone 500mg Injection in PRVC meeting please see attached.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 27-June 2025 vide application TID: P9G-HTY-WMJJ.	
	Decision	
	Approved	
578	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	FESTEL LABORATORIES THOKAR NIAZ BAIG , MULTAN ROAD, LAHORE. (000556)
	Application Form Dy. No / Tracking ID & date of submission	(NQN-WHM-UB26, 2026-02-03)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	CEFEST 1g INJECTION IV
	Label Claim	Each Vial contains: Ceftriaxone as sodium.....1g.
	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)	Esticef Injection 1g by M/s Aulton Pharmaceutical, Hattar
	Pharmacotherapeutic Group of (API)	Data Already Approved in PRVC meeting , Please see attached.
	Name, address of Manufacturing site:	Nicholas Pharmaceuticals.-Plot # 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad-

	The status in reference regulatory authorities	Rocephin 1g Powder for Solution for Injection or Infusion, MHRA UK
	Detail of previous approval	Magxone 1g Injection in PRVC meeting please see attached.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 27-June 2025 vide application TID: B4B-YPA-G276.	
579	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(W2L-2TZ-JA2H, 2026-02-16)
	Detail of Fee Submitted	93000.0, 2024-11-21,
	The proposed proprietary name / brand name	Zoledon 4mg/5ml infusion
	Label Claim	Each 5ml vial contains: Zoledronic acid as monohydrate.....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 30°C
	For generic drugs (me-too Status)	Zoledronic acid Normon 4mg/5ml Injection by Merixil Pharma Islamabad (Importer) (082059)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM, Chak Beli Road, Rawat,Islamabad-Pakistan-
	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, Minutes of 333rd meeting of Registration Boa
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
580	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Rite Bio Sciences (Pvt) Ltd. Plot No. 9-A, Street No. N-5, RCCI Rawat (000871)
	Application Form Dy. No / Tracking ID & date of submission	(N5H-ENY-82AU, 2026-02-16)
	Detail of Fee Submitted	97200, 2026-01-13,
	The proposed proprietary name / brand name	Ozapine Flash-10mg Orodispersible Tablets
	Label Claim	Each Orodispersible Tablet Contains; Olanzapine 10mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's,20's,30's,40's& 100's-As per SRO
	Shelf Life (Unit)	3 YearRoom Temperature
	For generic drugs (me-too Status)	Me too Status: Registered in Pakistan Brand Name: Psyclan 10mg Orodispersible Tablets Manufacturer: PharmEvo Private Limited. Address: 402 Suite, Business Avenue, Shahrah-e-Faisal Block 6 P.E.C.H.S.
	Pharmacotherapeutic Group of (API)	Anti-psychotic
	Name, address of Manufacturing site:	SOLARIS LIFE SCIENCES (PVT.) LTD-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-
	The status in reference regulatory authorities	SRA Registration Status: Registered in United State. Brand Name: Zyprexa 10mg Orodispersible Tablets Manufacturer: Eli Lilly and Company. Address: Lilly Corporate Center Indianapolis, IN 46285 (317) 276-2000.
	Detail of previous approval	M-339, Enzapin 10mg ODT 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	
581	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Rite Bio Sciences (Pvt) Ltd. Plot No. 9-A, Street No. N-5, RCCI Rawat (000871)
	Application Form Dy. No / Tracking ID & date of submission	(7HQ-8WU-J62V, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-18,
	The proposed proprietary name / brand name	Latrate-2.5mg Tablets
	Label Claim	Each film coated tablet contains: Letrozole.....2.5mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's,20's,30's,40's& 100's-As per SRO
	Shelf Life (Unit)	3 YearRoom Temperature

	For generic drugs (me-too Status)	Me To Registration Status: Registered in Pakistan Brand Name: Selet 2.5mg Tablets Manufacturer: Seraph Pharmaceutical Address: Plot no. 210, Industrial Triangle, Kahuta Rd, Islamabad
	Pharmacotherapeutic Group of (API)	Nonsteroidal aromatase inhibitors
	Name, address of Manufacturing site:	SOLARIS LIFE SCIENCES (PVT.) LTD-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-
	The status in reference regulatory authorities	SRA Registration Status: US FDA Approved New Drug Application (NDA): 020726 Company: Novartis Pharmaceutical corporation Address: Suurstoffi 14, 6343 Rotkreuz, Switzerland Brand Name: Femara 2.5mg Tablets Marketing status: Prescription
	Detail of previous approval	Leteron 2.5mg Tablet, 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	
582	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Rite Bio Sciences (Pvt) Ltd. Plot No. 9-A, Street No. N-5, RCCI Rawat (000871)
	Application Form Dy. No / Tracking ID & date of submission	(AWS-1PG-44G8, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	Turam 37.5/ 325 mg Tablet
	Label Claim	Composition: Each film coated tablet contains; Tramadol HCl..... 37.5 mg Paracetamol..... 325 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	3 YearRoom Temperature
	For generic drugs (me-too Status)	Product Name: Tonoflex-p Tablet Composition: Each film coated tablet contains; Tramadol HCl..... 37.5 mg Paracetamol..... 325 mg Sami Pharmaceutical Pakistan (Pvt.) ltd
	Pharmacotherapeutic Group of (API)	Analgesic & antipyretic
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	SRA Registration Status: USFDA approved Brand Name: Ultracet® Tablet Manufacturer: by Janssen
	Detail of previous approval	Minutes of 335th meeting of Registration Board (25th April, 2024), PARADOL D 37.5/325mg

		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	
583	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Rite Bio Sciences (Pvt) Ltd. Plot No. 9-A, Street No. N-5, RCCI Rawat (000871)
	Application Form Dy. No / Tracking ID & date of submission	(GPZ-MH2-52X6, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-01-13,
	The proposed proprietary name / brand name	PEPSE INSTA 20mg+1100mg Capsule
	Label Claim	Each capsule contains: Omeprazole 20mg Sodium bicarbonate 1100mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's 10's 14's-As per SRO
	Shelf Life (Unit)	3 YearRoom Temperature
	For generic drugs (me-too Status)	Me too Status: Registered in Pakistan Brand Name: TEpH Insta 20mg/1100mg capsules Manufacturer: Sami Pharmaceuticals (Pvt.) Ltd. Address: off Hub River Road, F-95, Sindh Industrial Trading Estate, Kar
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic Group: proton pump inhibitors (PPIs)
	Name, address of Manufacturing site:	SOLARIS LIFE SCIENCES (PVT.) LTD-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-
	The status in reference regulatory authorities	SRA Registration Status: Registered in USA. Brand Name: Zegerid 20mg/1,100mg capsule Manufacturer: Salix Pharma USA. Address:Bridgewater Township, New Jersey, United States..
	Detail of previous approval	M-344, omesol plus 20mg/1100mg Capsule
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

584	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Rite Bio Sciences (Pvt) Ltd. Plot No. 9-A, Street No. N-5, RCCI Rawat (000871)
	Application Form Dy. No / Tracking ID & date of submission	(MJA-GAJ-8YBU, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-18,
	The proposed proprietary name / brand name	Famocid-40mg/5ml Dry Suspension
	Label Claim	Each 5ml Contains; FAMOTIDINE 40mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml,60ml, 120ml-As per SRO
	Shelf Life (Unit)	3 YearRoom Temperature
	For generic drugs (me-too Status)	Me too Status: Registered in Pakistan Brand Name: Polypep 40mg/5ml Dry Suspension Manufacturer: Wilson's Pharmaceuticals Pvt., Ltd. Address: 387-388, I-9 Industrial Area, Islamabad
	Pharmacotherapeutic Group of (API)	Histamine H2 receptor antagonist
	Name, address of Manufacturing site:	SOLARIS LIFE SCIENCES (PVT.) LTD-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	refer to minutes of meeting
	Documents for the procurement of API with approval from DRAP (in case of Import)	refer to minutes of meeting
	Pharmaceutical Equivalence and Comparative Dissolution Profile	refer to minutes of meeting
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	refer to minutes of meeting
	The status in reference regulatory authorities	SRA Registration Status: Registered in USA. Brand Name: Pepcid for oral suspension Manufacturer: Salix Pharma USA Address: 400 Somerset Corporate Boulevard. Bridgewater, NJ 08807
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	section approval attached in module 1
585	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
585	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Rite Bio Sciences (Pvt) Ltd. Plot No. 9-A, Street No. N-5, RCCI Rawat (000871)
	Application Form Dy. No / Tracking ID & date of submission	(QSQ-P96-1EZU, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	Turam 50mg/ml Injection
	Label Claim	Each 2ml contains; Tramadol HCl.....100 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Product Name: Tonoflex 50mg/ml Injection Registration Number: 053224 Manufacturer :Sami Pharmaceutical Pakistan (Pvt.) ltd
	Pharmacotherapeutic Group of (API)	Opioid Analgesic
	Name, address of Manufacturing site:	Biogen Life Sciences -8-km Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	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.	
586	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Rite Bio Sciences (Pvt) Ltd. Plot No. 9-A, Street No. N-5, RCCI Rawat (000871)
	Application Form Dy. No / Tracking ID & date of submission	(UPX-B27-4R9A, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-18,
	The proposed proprietary name / brand name	Onderon Injection
	Label Claim	Each 2ml ampoule contains: Ondansetron HCl Dihydrate Eq. to Ondansetron.....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Brand Name: Onset Injection 4mg/2ml Manufacturer: Pharmedic Laboratories Strength & Composition: Each 2ml ampoule contains: Ondansetron HCl Dihydrate Eq. to Ondansetron.....4mg Pack Size: 2mlx1's
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) Receptor Antagonist

	Name, address of Manufacturing site:	Sharooq Pharmaceuticals -21-Km, Ferozepur Road Lahore Pakistan-
	The status in reference regulatory authorities	UKMHRA Approved Brand Name: Ondansetron Injection 2mg/ml Marketing Authorization Holder Generics [UK] Limited t/a Mylan
	Detail of previous approval	Dantron 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	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
587	Application Form Dy. No / Tracking ID & date of submission	(QUB-Y8Q-LZ3V, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	NORISTA 5mg Tablet
	Label Claim	Each Uncoated Tablet Contains: Norethisterone (USP).....5mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearReal time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	For generic drugs (me-too Status)	Brand Name of Approved Medicines Postpon-M Tablet Manufacturer OBS Karachi Strength 5mg Tablet Composition Each tablet contains: Norethisterone.....5 mg Registration Number 073532 Dosage Form Tablet
	Pharmacotherapeutic Group of (API)	Progestins
	Name, address of Manufacturing site:	M/S Wnsfeild Pharmaceuticals, -Plot No. 122, Block - A, Phase - V, Industrial Estate, Hattar, KPK, Pakistan-
	The status in reference regulatory authorities	www.medicines.org.uk/emc/product/1494/smpc#g
	Detail of previous approval	Norista 5mg 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	
588	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(GM8-QNT-HJW6, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-26,
	The proposed proprietary name / brand name	METHYLL 500mg Injection
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....500Mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 25 C
	For generic drugs (me-too Status)	Brand Name of Approved Medicines Solu Medrol Injection Manufacturer Pfizer Pakistan Strength 40mg, 125mg, 500mg, 1gm Composition Each vial contains:- Methylprednisolone Sodium succinate.....
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	M/S Wenovo Pharmaceuticals, -Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi-
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Methyl 500mg Injection Minutes for 339th meeting of Registration Board
589	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
589	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(QMG-JPN-EZ63, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-26,
	The proposed proprietary name / brand name	METHYLL 1000mg Injection
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (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 25 C
	For generic drugs (me-too Status)	Brand Name of Approved Medicines Solu Medrol Injection Manufacturer Pfizer Pakistan Strength 40mg, 125mg, 1000mg, 1gm Composition Each vial contains:- Methylprednisolone Sodium succinate.....
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	M/S Wenovo Pharmaceuticals, -Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi-
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Methyl 1g Injection Minutes for 339th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
590	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Ashrafsons Pharmaceutical (Pvt) Ltd. Plot No. 40 Road No. R-2 Industrial Estate Gadoon, Amazai, Swabi (000947)
	Application Form Dy. No / Tracking ID & date of submission	(WTZ-LZ4-5V62, 2026-03-05)
	Detail of Fee Submitted	97200, 2026-02-23,
	The proposed proprietary name / brand name	Tomoflex-P
	Label Claim	Each film coated tablet contains: Tramadol HCL.....37.5mg Paracetamol.....325mg
	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)	Tonoflex by Sami
	Pharmacotherapeutic Group of (API)	Analgesic
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 1, Al Badar Industrial Estate, Phase II Sheikhpura road Lahore-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	345th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the	

	Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
591	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Evolution Pharmaceuticals (Pvt.) Ltd. Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. (000867)
	Application Form Dy. No / Tracking ID & date of submission	(WV7-6B1-TVY9, 2025-03-04)
	Detail of Fee Submitted	93000.0, 2024-10-08,
	The proposed proprietary name / brand name	Evocure 100mg/5ml Injection
	Label Claim	Each 5ml ampoule contains Iron hydroxide sucrose eq. to elemental iron 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 Yeartore below 30°C. Protect from light. Reconstituted solution may be stored at 25°C for 24 hours or between 2-8°C for 7 days.
	For generic drugs (me-too Status)	Brand Name: G-FER Injection Registration holder: Global Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL Plot # 210, Industrial Trian-Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan-
	The status in reference regulatory authorities	Brand Name Venofer 20 mg iron /mL Marketing Authorization holder: Vifor France 100-101 Terrasse Boieldieu Tour Franklin La Défense 892042 Paris La Défense Cedex France Regulatory Authority: Medicines and Healthcare products Regulatory Agency (MHRA) of UK
	Detail of previous approval	103717 Seros-IV100mg/5mlInjection, No.F-119-PRVC/2024(PR-II)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 16-May 2024.	
	Decision	
	Approved	
592	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Focus & Rulz Pharmaceuticals (Pvt) Ltd 44 - Industrial Triangle, Kahuta Road (000628)
	Application Form Dy. No / Tracking ID & date of submission	(XLV-U5S-ZDEU, 2025-10-17)
	Detail of Fee Submitted	97200, 2025-10-13,
	The proposed proprietary name / brand name	Mecofer 500mcg/ml Injection
	Label Claim	Each 1ml Ampoule contains: Mecobalamin 500mcg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 5's (1ml)-As per SRO
	Shelf Life (Unit)	2 YearRoom temperature
	For generic drugs (me-too Status)	Mecomax Injection 500mcg/ml injection
	Pharmacotherapeutic Group of (API)	Coenzyme –Type vitamin B12
	Name, address of Manufacturing site:	M/s SERAPH PHARMACEUTICAL-Plot No 210, Industrial Triangle, Kahuta road, Islamabad-Pakistan-
	The status in reference regulatory authorities	Mecobalamin (500mcg) injection PMDC Approved
	Detail of previous approval	Adenomin 500mcg/ml Injection in 119th meeting of PRVC
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 16-May 2024.	
593	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Focus & Rulz Pharmaceuticals (Pvt) Ltd 44 - Industrial Triangle, Kahuta Road (000628)
	Application Form Dy. No / Tracking ID & date of submission	(4JM-JDN-HVBD, 2025-10-17)
	Detail of Fee Submitted	97200, 2025-10-13,
	The proposed proprietary name / brand name	Tradol 100mg/2ml Injection
	Label Claim	Each 2ml Ampoule contains; Tramadol hydrochloride - 100mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2ml x 5's , 2ml x 10's-As per SRO
	Shelf Life (Unit)	2 YearRoom temperature
	For generic drugs (me-too Status)	Tramal 100mg/2ml injection
	Pharmacotherapeutic Group of (API)	Opiate (narcotic) analgesics
	Name, address of Manufacturing site:	M/s SERAPH PHARMACEUTICAL -Plot No 210, Industrial Triangle, Kahuta road, Islamabad-Pakistan -

	The status in reference regulatory authorities	Zydol 100mg/2ml
	Detail of previous approval	Ovodol 100mg/2ml Injection in 119th meeting of PRVC
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 16-May 2024.	
	Decision	
	Approved	
594	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Focus & Rulz Pharmaceuticals (Pvt) Ltd 44 - Industrial Triangle, Kahuta Road (000628)
	Application Form Dy. No / Tracking ID & date of submission	(BT4-7M1-QHXX, 2025-10-17)
	Detail of Fee Submitted	97200, 2025-10-13,
	The proposed proprietary name / brand name	Ketalon 30mg/ml Injection
	Label Claim	Each 1 ml Ampoule Contains: Ketorolac Tromethamine...30mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1ml x 5's , 1ml x 10's-As per SRO
	Shelf Life (Unit)	2 YearRoom temperature
	For generic drugs (me-too Status)	Toralac 30mg/ml injection
	Pharmacotherapeutic Group of (API)	Nonsteroidal anti-inflammatory drugs
	Name, address of Manufacturing site:	M/s SERAPH PHARMACEUTICAL -Plot No 210, Industrial Triangle, Kahuta road, Islamabad-Pakistan-
	The status in reference regulatory authorities	Toradol 30mg/ml injection
	Detail of previous approval	Cilokat 30mg/ml injection in 119th meeting of PRVC
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The cross-referred product was approved in PRV dated 16-May 2024.	
	Decision	
	Approved	
595	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDICRAFT PHARMACEUTICAL PVT LIMITED 126-B INDUSTRIAL ESTATE

		HAYATABAD PESHAWAR (000390)
	Application Form Dy. No / Tracking ID & date of submission	(RE8-BPL-AZDQ, 2026-02-18)
	Detail of Fee Submitted	97200, 2026-02-06,
	The proposed proprietary name / brand name	DydroTron 10mg Tablet
	Label Claim	Each film coated tablet contains 10 mg of Dydrogesterone
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	3 YearStore at room temperature below 30
	For generic drugs (me-too Status)	me too
	Pharmacotherapeutic Group of (API)	Genito Urinary system and sex hormones.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot #01,Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-
	The status in reference regulatory authorities	US FDA APPROVED(Mylan IRE Healthcare Limited)
	Detail of previous approval	TABLET D-GEST 10 MG, Refer to product approved in 336th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
596	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	(YLW-J9D-LZVY, 2026-03-02)
	Detail of Fee Submitted	97200, 2026-01-05,
	The proposed proprietary name / brand name	FLUCINIC TOPICAL OIL 0.01%
	Label Claim	Each gram contains:
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml,60ml,100ml,120ml,-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Celsius
	For generic drugs (me-too Status)	Derma smooth by /s Valor Pharma
	Pharmacotherapeutic Group of (API)	Data already approved in 347 MoM , please see attached.
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Derma-Smoothe/FS ,FDA Approved
	Detail of previous approval	Derma cal Topical Oil in 347 MoM.
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
597	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	(V5R-YGD-3MN3, 2026-03-11)
	Detail of Fee Submitted	97200, 2026-02-11,
	The proposed proprietary name / brand name	Ketonic Tablets
	Label Claim	Each film coated tablet contains: α -Ketoanalogue to isoleucine (Calcium-salt) ... 67 mg α -Ketoanalogue to leucine (Calcium-salt) ... 101 mg α -Ketoanalogue to phenylalanine (Calcium-Salt) 68 mg α -Ketoanalogue to valine (Calcium-Salt) 86 mg α -hydroxyanalogue to DL-methionine (Calcium-Salt)....59 mg L-lysine acetate...105mg corresponding to L-lysine 75 mg L-threonine 53 mg L-tryptophan 23 mg L-histidine 38 mg L-tyrosine 30 mg Total nitrogen content per tablet 36 mg Calcium content per tablet 1.25mmol = 50 mg
	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 Celsius
	For generic drugs (me-too Status)	Ketoalfa Tablet by M/s Genome Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Data already approved in 336 MoM , please see attached.
	Name, address of Manufacturing site:	SOLARIS LIFE SCIENCES (PVT.) LTD-Plot No. 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi-
	The status in reference regulatory authorities	Ketosteril Tablets by M/s Fresenius Kabi, Germany , Bfarm Approved
	Detail of previous approval	Ketorien Tablet in 336 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	

598	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Wallace Pharma Evolutions Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951)
	Application Form Dy. No / Tracking ID & date of submission	(ZHA-PGQ-ZSST, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-10-31,
	The proposed proprietary name / brand name	Viglo 25mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate (USP).....25mg (Product complies 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 25°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	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	Viglo Tablet, DRB 351
	Evaluation Remarks	
599	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(39S-1YZ-UEWB, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-22,
	The proposed proprietary name / brand name	UroCitra Tablets 10mEq
	Label Claim	UroCitra Tablets 10mEq Each extended-release tablet contains: Potassium Citrate 10mEq
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 YearBelow 30
	For generic drugs (me-too Status)	Uro-K
	Pharmacotherapeutic Group of (API)	Urinary Alkanizing Agent
	Name, address of Manufacturing site:	M/s Global Pharmaceuticals Pakistan-Plot No. 8,Street No,S-8 RCCI Industrial Estate Rawat-
	The status in reference regulatory authorities	USFDA

	Detail of previous approval	Registration of this product transferred from Global Pharmaceuticals (PVT.) Ltd DML No. 000417 to GI
	Evaluation Remarks	
	The cross-referred product was approved having tracking ID 62X-5LX-Z48G. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
600	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Rotex Pharma Pvt Ltd Plot No 206 207 Industrial Triangle Kahuta Road (000651)
	Application Form Dy. No / Tracking ID & date of submission	(5PG-86G-YUW4, 2026-02-18)
	Detail of Fee Submitted	97200, 2026-01-14,
	The proposed proprietary name / brand name	Vonza
	Label Claim	Each Film Coated Tablet Contains; Vonoprazan Fumarate equivalent to vonoprazan.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	24 MonthBelow 30C
	For generic drugs (me-too Status)	Vonozan Tablets 10 mg, Getz Pharma
	Pharmacotherapeutic Group of (API)	Potassium Competitive Acid Blocker
	Name, address of Manufacturing site:	M/S Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi -
	The status in reference regulatory authorities	USFDA Approved, Voquezna 10mg Tablet, Phathom
	Detail of previous approval	Tracking ID: 64U-JMV-63MP
	Evaluation Remarks	
	The cross-referred product was approved having Tracking ID64U-JMV-63MP. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
601	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)

	Application Form Dy. No / Tracking ID & date of submission	(EQN-9G6-B1NW, 2026-03-04)
	Detail of Fee Submitted	97200, 2026-02-18,
	The proposed proprietary name / brand name	Ageston 10mg Tablet
	Label Claim	Each film coated tablet contains: Dydrogesterone 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,40's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Dydrogest 10mg Tablet by M/s Aspin Pharma
	Pharmacotherapeutic Group of (API)	Genitourinary system and sex hormones
	Name, address of Manufacturing site:	M/s. OBS Pharma (Pvt) Ltd.-108, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore-
	The status in reference regulatory authorities	Nalvee (MHRA Approved)
	Detail of previous approval	Dydrogest 10mg Tablet, Tracking ID: 25D-2SH-M8LD
	Evaluation Remarks	
	The cross referred product was approved in PRV via Tracking ID 25D-2SH-M8LD.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
602	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(ESE-9QD-1QRP, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-21,
	The proposed proprietary name / brand name	Toropin 30mg/ml Injection
	Label Claim	Each ml contains: Ketorolac tromethamine 30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Toralac 30mg/ml injection Global Pharmaceuticals Pakistan
	Pharmacotherapeutic Group of (API)	pyrrolo-pyrrole group of nonsteroidal anti-inflammatory drugs
	Name, address of Manufacturing site:	M/s Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	Toradol 30mg/ml injection Roche Palo Alto LLC , California, US FDA Approved drugs

	Detail of previous approval	PRVC meeting: F-119-PRVC/2024(PRII)
	Evaluation Remarks	
	The cross-referred product was approved in PRVC No. F-119-PRVC/2024 (PR-II).In light of Registration Board’s decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
603	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	LEAMA CHEMI PHARMA (PVT) LTD 37-A HAYATABAD INDUSTRIAL ESTATE PESHAWAR (000404)
	Application Form Dy. No / Tracking ID & date of submission	(6JH-PB6-GGW9, 2026-03-09)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	Lemafil 100mg
	Label Claim	Each film coated Tablet contains: Sildenafil Citrate 140.508 mg eq. to sildenafil 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4s and 1x10s-As per SRO
	Shelf Life (Unit)	2 Year30 C
	For generic drugs (me-too Status)	ripple 100 mg tablets
	Pharmacotherapeutic Group of (API)	phosphodiesterase type 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	SOLARIS LIFE SCIENCES (PVT.) LTD-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Ripple 100mg Tablets, (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	
604	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(7LX-XGM-V8E9, 2026-03-09)

	Detail of Fee Submitted	97200, 2026-02-27,
	The proposed proprietary name / brand name	Merogab 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	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd. -129-Sunder Industrial Estate, Raiwind Road, Lahore, Pakistan-
	The status in reference regulatory authorities	Manufacturer Name: Daiichi Sankyo Co., Ltd Brand Name & Strength: Tarlige Tablets 5mg PMDA Approved
	Detail of previous approval	344th 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	
605	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	LEAMA CHEMI PHARMA (PVT) LTD 37-A HAYATABAD INDUSTRIAL ESTATE PESHAWAR (000404)
	Application Form Dy. No / Tracking ID & date of submission	(YL7-2TG-GBGX, 2026-03-09)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	Lemafil 50 mg
	Label Claim	Each film coated Tablet contains: Sildenafil Citrate 70.225 mg eq. to sildenafil 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4s and 1x10s-As per SRO
	Shelf Life (Unit)	2 Year30 C
	For generic drugs (me-too Status)	ripple 50 mg tablets
	Pharmacotherapeutic Group of (API)	phosphodiesterase type 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	SOLARIS LIFE SCIENCES (PVT.) LTD-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Ripple 50mg Tablets, (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	
606	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(5R1-HJD-N6A7, 2026-03-10)
	Detail of Fee Submitted	97200, 2026-02-27,
	The proposed proprietary name / brand name	Dupaton 10mg Tablets
	Label Claim	Each film coated tablet contains Dydrogesterone.....10 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Dydrogest 10mg Tablet. Registration holder: OBS Pakistan (Pvt) Ltd., C-14 Mangopir Road SITE Karachi. , Karachi.
	Pharmacotherapeutic Group of (API)	GENITO URINARY SYSTEM AND SEX HORMONES
	Name, address of Manufacturing site:	SKYWIN PHARMACEUTICALS-Plot # 01, Al Badar Industrial Estate, Phase II Sheikhpura Road Lahore.-
	The status in reference regulatory authorities	Duphaston 10 mg film-coated tablets. 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	336th Meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Skywin Pharmaceuticals Pvt. Ltd Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (000971)

	Application Form Dy. No / Tracking ID & date of submission	(NQE-VT4-RBWR, 2026-03-10)
	Detail of Fee Submitted	97200, 2026-02-11,
	The proposed proprietary name / brand name	Desosky Syrup
	Label Claim	Each ml contains: Desloratadine 0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60ml, 90ml, 120ml-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Desora Syrup of M/s Continental Pharmaceuticals
	Pharmacotherapeutic Group of (API)	tricyclic antihistamine
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Desloratadine 0.5mg/ml Oral Solution of M/s Accord Healthcare Limited Euro House, Euro Business Park, Little Island Cork T45, K587, Ireland (HPRA Approved)
	Detail of previous approval	Doara Syrup - 348th 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.	
608	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
	Application Form Dy. No / Tracking ID & date of submission	(491-WJR-NS49, 2026-03-11)
	Detail of Fee Submitted	97200, 2026-03-04,
	The proposed proprietary name / brand name	P-Mol Injection for Infusion 1000mg/100ml
	Label Claim	Each 100ml contains: Paracetamol.....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml vial-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Aceject Injection for Infusion by Cunningham Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Analgesic, Antipyretic
	Name, address of Manufacturing site:	Cunningham Pharmaceuticals (Pvt.) Ltd.-Plot No.81, Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	Acetaminophen 1gm/100ml by US-FDA
	Detail of previous approval	Param Injection for Infusion 10mg/ml;100ml (344th DRB Meeting)

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
609	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	INVENTOR PHARMA PVT LTD Plot No. K-196 S.I.T.E, Super Highway Phase-II (000866)
	Application Form Dy. No / Tracking ID & date of submission	(77Q-1VJ-DA71, 2026-03-11)
	Detail of Fee Submitted	97200, 2026-02-16,
	The proposed proprietary name / brand name	Cit-In Injection 1g/4ml
	Label Claim	Each 4ml ampoule contains Citicoline sodium eq. to Citicoline.....1000mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1x 5's, 1 x 1's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30° C
	For generic drugs (me-too Status)	Citolin 1gm Injection Global Pharma
	Pharmacotherapeutic Group of (API)	Nootropic
	Name, address of Manufacturing site:	Fortune Pharma Pvt. Ltd.-Plot # K/201, SITE Superhighway SITE-II Karachi-
	The status in reference regulatory authorities	SOMAZINA 1000 mg solution for injection-Spain
	Detail of previous approval	Citifor Injection 1g/4ml (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	
610	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	(A7N-9Z9-TX83, 2026-03-11)
	Detail of Fee Submitted	97200, 2026-03-05,
	The proposed proprietary name / brand name	Soldin 4mg Capsules

	Label Claim	Each Capsule Contains; Silodosin 4mg (As per Innovator Specifications).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 10's-As per SRO, 2 X 10'S -As per SRO
	Shelf Life (Unit)	2 Year 15°C - 30°C
	For generic drugs (me-too Status)	Silorap 4mg capsule by Getzpharma (Pvt). Ltd.
	Pharmacotherapeutic Group of (API)	alpha-1 adrenergic receptor antagonists (also known as alpha-blockers or alpha-1 blockers)
	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. (Rapaflo 4mg capsule).
	Detail of previous approval	SILOTON 4mg CAPSULE (M-344)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
611	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	(AAZ-H1Z-X4H2, 2026-03-11)
	Detail of Fee Submitted	97200, 2026-03-03,
	The proposed proprietary name / brand name	Cefeze Capsules 400mg
	Label Claim	Each Capsule contains: Cefixime as trihydrate.....400mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10's (2x5s)-Controlled, 5's (1x5s)-Controlled
	Shelf Life (Unit)	2 Year Do not store above 30°C
	For generic drugs (me-too Status)	Brand Name: Tucana capsules 400mg Manufactured by: M/s NovaMed Pharmaceuticals (Pvt) Ltd Marketed by: M/s Abbott Laboratories (Pakistan) Ltd
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins
	Name, address of Manufacturing site:	M/s NovaMed Pharmaceuticals (Pvt.) Ltd.-28-KM Ferozepur Road, Lahore-
	The status in reference regulatory authorities	Brand Name: Suprax Capsules 400mg Approval granted to : Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202 United States
	Detail of previous approval	Product Name: ICEF Capsules 400mg Meeting NO: 316th
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
612	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	(BWM-4QY-N5PU, 2026-03-11)
	Detail of Fee Submitted	97200, 2026-02-25,
	The proposed proprietary name / brand name	Lasmit 50 mg Tablet
	Label Claim	Each Film Coated Tablet contains Lasmiditan hemisuccinate equivalent to Lasmiditan 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 Year Below 30°C
	For generic drugs (me-too Status)	Wimits Pharmaceuticals Pvt Ltd
	Pharmacotherapeutic Group of (API)	Lasmiditan is used to treat the symptoms of migraine headaches (severe throbbing headaches that sometimes are accompanied by nausea and sensitivity to sound and light). Lasmiditan is in a class of medications called selective serotonin receptor agonists.
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) Limited -Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore -
	The status in reference regulatory authorities	REYVOW (lasmiditan) tablet 50 mg
	Detail of previous approval	Lasmi 50 mg Tablet, M-348
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
613	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	INVENTOR PHARMA PVT LTD Plot No. K-196 S.I.T.E, Super Highway Phase-II (000866)

	Application Form Dy. No / Tracking ID & date of submission	(DTG-6W5-2RSM, 2026-03-11)
	Detail of Fee Submitted	97200, 2026-02-16,
	The proposed proprietary name / brand name	Icoz 100mg Capsule
	Label Claim	Each capsule contains: Itraconazole (as IR Pellets) 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	24 MonthDo not store above 25°C.
	For generic drugs (me-too Status)	Icon 100g Capsule
	Pharmacotherapeutic Group of (API)	Anti Fungal
	Name, address of Manufacturing site:	Fortune Pharma Pvt. Ltd.-Plot # K/201, SITE Superhighway SITE-II Karachi-
	The status in reference regulatory authorities	Itraconazole 100mg Capsules USA
	Detail of previous approval	Foritra Capsule 100mg (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.	
614	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(N3H-41T-VBRS, 2026-03-11)
	Detail of Fee Submitted	97200, 2026-02-27,
	The proposed proprietary name / brand name	LEGOLIX 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; 2x7's; 2x10's; 3x10's-De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30 degree centigrade
	For generic drugs (me-too Status)	Lingolix 100mg Tablets
	Pharmacotherapeutic Group of (API)	Pharmaceutical
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt) Ltd-Plot No.313 Industrial Triangle Kahuta Road Islamabad -
	The status in reference regulatory authorities	Yestly by Theramex Ireland Limited
	Detail of previous approval	Linza 100mg Tablets (Linzagolix), DRB-351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product	

	formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
615	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
	Application Form Dy. No / Tracking ID & date of submission	(PUN-AE9-5AAJ, 2026-03-11)
	Detail of Fee Submitted	97200, 2026-02-21,
	The proposed proprietary name / brand name	Tacryl XR Capsule 0.5mg
	Label Claim	Each prolonged release capsule contains: Tacrolimus (as monohydrate) 0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	FIXGRAF XR CAPSULE (Mfg. by: Genome Pharmaceuticals (Pvt.) Ltd,)
	Pharmacotherapeutic Group of (API)	Calcineurin inhibitors
	Name, address of Manufacturing site:	Genome Pharmaceuticals (Pvt.) Ltd,-Plot No. 16/1, Phase-IV, Industrial Estate Hattar, Dist: Haripur (KPK)-PAKISTAN-
	The status in reference regulatory authorities	ASTAGRAF XL (CAPSULE, EXTENDED RELEASE;ORAL) - USFDA Approved
	Detail of previous approval	FIXGRAF 0.5mg XR CAPSULE , 351st 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.	
616	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd , Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(QZJ-D34-JG1J, 2026-03-11)
	Detail of Fee Submitted	97200, 2026-02-25,
	The proposed proprietary name / brand name	Lasmit 100 mg Tablet
	Label Claim	Each Film Coated Tablet contains Lasmiditan hemisuccinate equivalent to Lasmiditan

		 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Lasmiray 100 mg Tablet
	Pharmacotherapeutic Group of (API)	Lasmiditan is used to treat the symptoms of migraine headaches (severe throbbing headaches that sometimes are accompanied by nausea and sensitivity to sound and light). Lasmiditan is in a class of medications called selective serotonin receptor agonists
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) Limited -Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore -
	The status in reference regulatory authorities	REYVOW (lasmiditan) tablet 100 mg
	Detail of previous approval	Lasmi 100 mg Tablet, M-348
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
617	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(T1B-B45-2J15, 2026-03-11)
	Detail of Fee Submitted	97200, 2026-02-27,
	The proposed proprietary name / brand name	LEGOLIX 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; 2x7's; 2x10's; 3x10's-De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30 degree centigrade
	For generic drugs (me-too Status)	Lingolix 200mg Tablets
	Pharmacotherapeutic Group of (API)	Pharmaceutical
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt) Ltd-Plot No.313 Industrial Triangle Kahuta road Islamabad.-
	The status in reference regulatory authorities	Yestly by Theramex Ireland Limited
	Detail of previous approval	Linza 200mg Tablets (Linzagolix), DRB-351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
618	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(UER-MW6-P1XG, 2026-03-11)
	Detail of Fee Submitted	97200, 2026-02-27,
	The proposed proprietary name / brand name	Merogab 10mg Tablet
	Label Claim	Each Film coated tablet contains: Mirogabalin besilate equivalent to Mirogabalin.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pai
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd. -129-Sunder Industrial Estate, Raiwind Road, Lahore, Pakistan-
	The status in reference regulatory authorities	Tarlige Tablets 10mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	344th 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	
619	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
	Application Form Dy. No / Tracking ID & date of submission	(X9S-P1U-W6D5, 2026-03-11)
	Detail of Fee Submitted	97200, 2026-02-21,
	The proposed proprietary name / brand name	Tacryl XR Capsule 1mg
	Label Claim	Each prolonged release capsule contains: Tacrolimus (as monohydrate) 1mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	3 x 10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	f
	Pharmacotherapeutic Group of (API)	Calcineurin inhibitors
	Name, address of Manufacturing site:	Genome Pharmaceuticals (Pvt.) Ltd,-Plot No. 16/1, Phase-IV, Industrial Estate Hattar, Dist: Haripur (KPK)-PAKISTAN-
	The status in reference regulatory authorities	ASTAGRAF XL (CAPSULE, EXTENDED RELEASE;ORAL) - USFDA Approved
	Detail of previous approval	FIXGRAF 1mg XR CAPSULE , 351st 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	
620	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	(YGM-67H-W8PT, 2026-03-11)
	Detail of Fee Submitted	97200, 2026-03-03,
	The proposed proprietary name / brand name	Cefeze DS Dry Suspension 200mg/5ml
	Label Claim	Each 5ml contains: Cefixime as trihydrate.....200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30ml-Controlled,60ml-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30°C
	For generic drugs (me-too Status)	Brand Name: Tucana Suspension 200mg/5ml Manufactured by: M/s NovaMed Pharmaceuticals (Pvt) Ltd Marketed by: M/s Abbott Laboratories (Pakistan) Ltd
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins
	Name, address of Manufacturing site:	M/s NovaMed Pharmaceuticals (Pvt.) Ltd.-28-KM Ferozepur Road, Lahore-
	The status in reference regulatory authorities	Brand Name: Suprax Suspension 200mg/5ml Approval granted to : Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202 United States
	Detail of previous approval	Product Name: ICEF Suspension 200mg/5ml Meeting NO: 308th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
621	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(DTJ-3LM-Z5BR, 2026-03-17)
	Detail of Fee Submitted	97200, 2025-09-08,
	The proposed proprietary name / brand name	Cenem IV Injection 250mg
	Label Claim	Each vial contains Imipenem as monohydrate 250mg Cilastatin as sodium 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's -De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 25 °C. Do not freeze the reconstituted solution.
	For generic drugs (me-too Status)	Cilapen 250mg Injection
	Pharmacotherapeutic Group of (API)	Imipenem: is a beta lactam antibiotic belonging to sub group of carbapenems. Cilastatin: Is a chemical compound which inhibits the human enzyme dehydropeptidase.
	Name, address of Manufacturing site:	M/S Bio-Next Pharmaceuticals-Plot # 50, St. No. S-10, RCCI Industrial Estate Rawat, Islamabad-Pakistan-
	The status in reference regulatory authorities	USA, Imipenem And Cilastatin by ACS DOBFAR (ANDA=090577)
	Detail of previous approval	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	
622	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	INVENTOR PHARMA PVT LTD Plot No. K-196 S.I.T.E, Super Highway Phase-II (000866)
	Application Form Dy. No / Tracking ID & date of submission	(1L3-V38-L51V, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-16,
	The proposed proprietary name / brand name	NALPRO INJECTION 10MG/ML

	Label Claim	Each 1ml ampoule contains: Nalbuphine Hydrochloride.....10mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1ml x 1's, 1ml x 5's 1ml x10's-As per SRO
	Shelf Life (Unit)	24 MonthStore at 25°C
	For generic drugs (me-too Status)	Kinz 10mg Injection Sami Pharma
	Pharmacotherapeutic Group of (API)	Opioid
	Name, address of Manufacturing site:	Fortune Pharma Pvt. Ltd.-Plot # K/201, SITE Superhighway SITE-II Karachi-
	The status in reference regulatory authorities	NUBAIN
	Detail of previous approval	Nulbux Injection 10mg/ml (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	
623	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(5BW-W4Z-9R3V, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-10,
	The proposed proprietary name / brand name	EGNIX INJECTION 40 MG
	Label Claim	EACH VIAL Contains: Omeprazole as sodium = 40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 X 1'S-De-Controlled
	Shelf Life (Unit)	2 Yearstore at room temperature
	For generic drugs (me-too Status)	RISEK INJECTION
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	MAY AND BAKER PVT LTD-45 KM DINA NATH MULTAN ROAD LAHORE-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	OMEBAK 40 MG DRY POWDER VIAL
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

624	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	INVENTOR PHARMA PVT LTD Plot No. K-196 S.I.T.E, Super Highway Phase-II (000866)
	Application Form Dy. No / Tracking ID & date of submission	(68P-DL4-9S9L, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-16,
	The proposed proprietary name / brand name	NALPRO INJECTION 20MG/ML
	Label Claim	Each 1ml ampoule contains: Nalbuphine Hydrochloride.....20mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1ml x 5's-As per SRO
	Shelf Life (Unit)	24 MonthStore at 25°C
	For generic drugs (me-too Status)	Kinz 20mg Injection SAMI Pharma
	Pharmacotherapeutic Group of (API)	Opioid
	Name, address of Manufacturing site:	Fortune Pharma Pvt. Ltd.-Plot # K/201, SITE Superhighway SITE-II Karachi-
	The status in reference regulatory authorities	NUBAIN
	Detail of previous approval	Nalfort Injection 20mg/ml (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.	
625	Decision	
	Approved	
	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	(9DQ-G2Z-ZULL, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-01-13,
	The proposed proprietary name / brand name	Itramac 100mg Capsule
	Label Claim	Each capsule contains: Itraconazole IR pellets equivalent to Itraconazole 100 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	28's-Controlled,4"s-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Rolac 100 mg Capsule – M/s Sami Pharmaceuticals (Reg. No. 024491)
	Pharmacotherapeutic Group of (API)	Anti-Fungal
	Name, address of Manufacturing site:	McOlson Research Laboratories (Pvt) Ltd. -26-Km, Lahore Sharikhpur Road, District Sheikhpura.-
	The status in reference regulatory authorities	Sporanox 100 mg Capsule – USFDA Approved

	Detail of previous approval	Sporamac 100 mg Capsules, 350th meeting of RB, page no. 551
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
626	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	World Biz Pharmaceuticals Company, Multan 340, Phase-II, Industrial Estate, Multan (000942)
	Application Form Dy. No / Tracking ID & date of submission	(BDN-M3V-D7R3, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-10,
	The proposed proprietary name / brand name	Dystone 10mg Tablet
	Label Claim	Each film coated tablet contains Dydrogesterone....10mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10-As per SRO,20-As per SRO,28-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Dydrogest 10mg Tablet, OBS Pakistan (Pvt) Ltd., C-14 Mangopir Road SITE Karachi. , Karachi.
	Pharmacotherapeutic Group of (API)	Sex hormones and modulators of the genital system, Pregnadien derivatives.
	Name, address of Manufacturing site:	SKYWIN PHARMACEUTICALS-Plot # 01, Al Badar Industrial Estate, Phase II Sheikhpura Road Lahore.-
	The status in reference regulatory authorities	Duphaston 10 mg film-coated tablets ® is Approved in HPRA of Ireland
	Detail of previous approval	TABLET D-GEST 10 MG, 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	
627	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)

	Application Form Dy. No / Tracking ID & date of submission	(JP3-15U-U38R, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-10,
	The proposed proprietary name / brand name	E-ZOOM INJECTION 40 MG
	Label Claim	Each vial Contains: Esomeprazole Sodium eq. to Esomeprazole = 40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 X 1'S-De-Controlled
	Shelf Life (Unit)	2 Yearstore at room temperature
	For generic drugs (me-too Status)	NEXUM INJECTION 40 MG
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	MAY AND BAKER PVT LTD-45 KM DINA NATH MULTAN ROAD LAHORE-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	"Esozium 40mg dry powder vial" 327 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	
628	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	INVENTOR PHARMA PVT LTD Plot No. K-196 S.I.T.E, Super Highway Phase-II (000866)
	Application Form Dy. No / Tracking ID & date of submission	(YAG-VXR-UMN1, 2026-03-26)
	Detail of Fee Submitted	97200, 2026-02-16,
	The proposed proprietary name / brand name	Monter Sachet 4mg
	Label Claim	Each sachet contains: Montelukast as sodium 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 7's, 1 x14's , 1 x 21's-As per SRO
	Shelf Life (Unit)	24 MonthStore at 25°C
	For generic drugs (me-too Status)	Myteka Sachet 4mg Hilton Pharma
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists (LTRAs)
	Name, address of Manufacturing site:	Fortune Pharma Pvt. Ltd.-Plot # K/201, SITE Superhighway SITE-II Karachi-
	The status in reference regulatory authorities	SINGULAIR® (MONTELUKAST SODIUM)
	Detail of previous approval	Lukafor sachet 4mg (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	
629	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Amarant Pharmaceuticals Private Limited 158 D. Tore, Gadap Road, Super Highway, Karachi (000584)
	Application Form Dy. No / Tracking ID & date of submission	(HD5-Q3L-7L6G, 2026-03-31)
	Detail of Fee Submitted	97200, 2026-02-18,
	The proposed proprietary name / brand name	Cometh 1MIU
	Label Claim	Each vial contains: Colistimethate Sodium 1 million International Units (IU) eq. to 80mg. (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 25 degree
	For generic drugs (me-too Status)	GENTHATE Injection 1 MIU
	Pharmacotherapeutic Group of (API)	polymyxin antibiotic
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Coly-Mycin USFDA
	Detail of previous approval	M-297 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	
630	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Amarant Pharmaceuticals Private Limited 158 D. Tore, Gadap Road, Super Highway, Karachi (000584)
	Application Form Dy. No / Tracking ID & date of submission	(V3W-256-JTPZ, 2026-03-31)
	Detail of Fee Submitted	97200, 2026-02-18,
	The proposed proprietary name / brand name	Alburant 20mg injection
	Label Claim	Each ml Contains: Nalbuphine HCl 20mg (Innovator Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO

	Shelf Life (Unit)	2 Yearbelow 30 degree
	For generic drugs (me-too Status)	Bional Injection 20mg/mL
	Pharmacotherapeutic Group of (API)	opioid agonist-antagonist analgesic
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-316 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	
631	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Amarant Pharmaceuticals Private Limited 158 D. Tore, Gadap Road, Super Highway, Karachi (000584)
	Application Form Dy. No / Tracking ID & date of submission	(YRR-YEH-V348, 2026-03-31)
	Detail of Fee Submitted	97200, 2026-02-18,
	The proposed proprietary name / brand name	Alburant 10mg injection
	Label Claim	Each ml Contains: Nalbuphine HCl 10mg (Innovator Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30 degree
	For generic drugs (me-too Status)	Bional Injection 10mg/mL
	Pharmacotherapeutic Group of (API)	opioid agonist-antagonist analgesic
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-316 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	
632	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Saibins Pharmaceuticals Plot No.316 Industrial Triangle Kahutta Road Islamabad (000773)
	Application Form Dy. No / Tracking ID & date of submission	(21S-X6L-GMJQ, 2024-11-19)
	Detail of Fee Submitted	93000.0, 2024-10-31,
	The proposed proprietary name / brand name	Saixone 500mg Injection
	Label Claim	Each Vial contains: Ceftriaxone Sodium equivalent to ceftriaxone----- 500mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 YearStore in cool and dry place below 30C
	For generic drugs (me-too Status)	Topcef Inj by Pride Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Bio-Labs (PVT.)Ltd-Plot#145 Industrial Triangle Kahuta road Islamabad-
	The status in reference regulatory authorities	MHRA and USFDA Approved
	Detail of previous approval	Celine 500mg Injection IV,327th 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.	
633	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Saibins Pharmaceuticals Plot No.316 Industrial Triangle Kahutta Road Islamabad (000773)
	Application Form Dy. No / Tracking ID & date of submission	(68P-JHV-VG1Y, 2024-11-19)
	Detail of Fee Submitted	93000.0, 2024-10-31,
	The proposed proprietary name / brand name	Saizole DS 100mg/5mL
	Label Claim	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30mL-As per SRO
	Shelf Life (Unit)	3 YearStore in cool and dry place below 30C
	For generic drugs (me-too Status)	Cefim suspension by Hilton Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Bio-Labs (PVT.)Ltd-PLOT#145 kahuta industrial Triangle Islamabad-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	VARICEF 100mg/5ml Dry Suspension,327
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
634	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Saibins Pharmaceuticals Plot No.316 Industrial Triangle Kahutta Road Islamabad (000773)
	Application Form Dy. No / Tracking ID & date of submission	(BL4-YWQ-1Y15, 2024-11-19)
	Detail of Fee Submitted	93000.0, 2024-10-31,
	The proposed proprietary name / brand name	Saixone 500mg Injection
	Label Claim	Each Vial Contains: Ceftriaxone sodium equivalent to Ceftriaxone -----500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 YearStore in cool and dry place below 30C
	For generic drugs (me-too Status)	Topcef Inj by Pride Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Bio-Labs (PVT.)Ltd-PLOT#145 industrial Triangle kahuta road Islamabad-
	The status in reference regulatory authorities	MHRA and USFDA Approved
	Detail of previous approval	Celine 500mg Injection,327th 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	
635	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Saibins Pharmaceuticals Plot No.316 Industrial Triangle Kahutta Road Islamabad (000773)
	Application Form Dy. No / Tracking ID & date of submission	(E62-RB6-49XH, 2024-11-19)
	Detail of Fee Submitted	93000.0, 2024-10-31,
	The proposed proprietary name / brand name	Saixone 250mg Injection
	Label Claim	Each Vial Contains: Ceftriaxone Sodium equivalent to Ceftriaxone -----250mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 YearStore in cool and dry place below 30C
	For generic drugs (me-too Status)	Topcef Inj by Pride Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Bio-Labs (PVT.)Ltd-PLOT#145 kahuta industrial Triangle Islamabad-
	The status in reference regulatory authorities	MHRA and USFDA Approved
	Detail of previous approval	Celine 250mg Injection IM,316th 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.	
636	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Saibins Pharmaceuticals Plot No.316 Industrial Triangle Kahutta Road Islamabad (000773)
	Application Form Dy. No / Tracking ID & date of submission	(QY7-D72-T1GA, 2024-11-19)
	Detail of Fee Submitted	93000.0, 2024-10-31,
	The proposed proprietary name / brand name	Saixone 1g Injection
	Label Claim	Each Vial Contains: Ceftriaxone Sodium equivalent to Ceftriaxone----- 1 g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 YearStore in cool and dry place below 30C
	For generic drugs (me-too Status)	Aventriax 1g Injection of M/s. Sanofi Aventis 050379
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Bio-Labs (PVT.)Ltd-PLOT#145 industrial Triangle kahuta road Islamabad-
	The status in reference regulatory authorities	MHRA and USFDA Approved
	Detail of previous approval	Ceftione Inj 1g ,308th 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	

637	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Saibins Pharmaceuticals Plot No.316 Industrial Triangle Kahutta Road Islamabad (000773)
	Application Form Dy. No / Tracking ID & date of submission	(UH6-M9Z-J4VE, 2024-11-19)
	Detail of Fee Submitted	93000.0, 2024-10-31,
	The proposed proprietary name / brand name	Saizole DS 200mg/5mL
	Label Claim	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30mL-As per SRO
	Shelf Life (Unit)	3 YearStore in cool and dry place below 30C
	For generic drugs (me-too Status)	Cefim suspension by Hilton Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/S Bio-Labs (PVT.)Ltd-PLOT#145 kahuta industrial Triangle Islamabad-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	VARICEF 200mg/5ml Dry Suspension,327
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
638	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pasteur & Fleming Pharma Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan (000945)
	Application Form Dy. No / Tracking ID & date of submission	(3V7-Z5V-N8YY, 2024-11-19)
	Detail of Fee Submitted	93000.0, 2024-11-08,
	The proposed proprietary name / brand name	Elergo Syrup 0.5mg/ml
	Label Claim	Each ml contains: Desloratadine 0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120ml-As per SRO,30ml-As per SRO,60ml-As per SRO,90ml-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	Neo-Antial Syrup by SAMI Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Clarinex Syrup by SCHERING, USA
	Detail of previous approval	Varidine 0.5mg/ml Syrup (Meeting 297th)

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
639	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(8D3-17W-SWDH, 2024-12-02)
	Detail of Fee Submitted	93000.0, 2024-11-19,
	The proposed proprietary name / brand name	Neucalopride 1mg Tablet
	Label Claim	Label Claim: Each film coated tablet contains: Prucalopride succinate equivalent to Prucalopride 1mg (Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 7's-As per SRO
	Shelf Life (Unit)	2 Yearstore at 25C
	For generic drugs (me-too Status)	Notogrity by Seraph pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Seraph Pharmaceutical -M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.-
	The status in reference regulatory authorities	TAKEDA PHARMS USA, Approved in FDA.
	Detail of previous approval	Notogrity 1mg tablet, 331th 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	
640	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pak Risen Pharmaceuticals Plot No. 3, Block B, Phase I-II, Industrial Estate, Hattar (000573)
	Application Form Dy. No / Tracking ID & date of submission	(8R7-GWM-3DPL, 2024-12-02)
	Detail of Fee Submitted	93000.0, 2024-11-25,
	The proposed proprietary name / brand name	OMERISE 40MG INJECTION

	Label Claim	Each vial Contains: Omeprazole as Sodium ...40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year15 to 30 room temperature
	For generic drugs (me-too Status)	Risek 40mg Injection M/s Getz Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s May & Baker (pvt) Ltd-45km, Dina Nath, Multan road, Lahore.-
	The status in reference regulatory authorities	Approved by EMA of Sandoz Limited, UK
	Detail of previous approval	Minutes of 322nd meeting of Registration Board (8th & 10th November,2022) Page No92
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
641	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Focus & Rulz Pharmaceuticals (Pvt) Ltd 44 - Industrial Triangle, Kahuta Road (000628)
	Application Form Dy. No / Tracking ID & date of submission	(D7Q-YAS-363P, 2024-04-30)
	Detail of Fee Submitted	75000.0, 2024-03-22,
	The proposed proprietary name / brand name	Omper Injection
	Label Claim	Each lyophilized Vial Contains: Omeprazole sodium eq. to Omeprazole.....40mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearBelow 25°C.
	For generic drugs (me-too Status)	Risek Injection 40mg
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs Pvt. Ltd-Plot #145, Industrial Triangle,Kahuta Road,Islamabad-
	The status in reference regulatory authorities	Omeprazole 40mg powder for solution for infusion by Sandoz A Novartis
	Detail of previous approval	Omepranext Injection 40mg IV,324th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
642	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pak Risen Pharmaceuticals Plot No. 3, Block B, Phase I-II, Industrial Estate, Hattar (000573)
	Application Form Dy. No / Tracking ID & date of submission	(ERN-R56-YWY8, 2024-12-02)
	Detail of Fee Submitted	93000.0, 2024-11-25,
	The proposed proprietary name / brand name	ESORISE 40MG INJECTION
	Label Claim	Each vial Contains: Esomeprazole Sodium eq. to Esomeprazole ...40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year15 TO 30 ROOM TEMPREATURE
	For generic drugs (me-too Status)	Nexum 40mg Injection M/s Getz Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s May & Baker Pharmaceuticals (Pvt.) Ltd-45 Km, Thokar Multan road, Lahore-
	The status in reference regulatory authorities	Approved by MHRA of Astrazeneca Limited, UK
	Detail of previous approval	Minutes of 327th meeting of Registration Board (13th April, 2023) page no 9
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
643	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhupura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(GNE-QLS-JB4V, 2024-12-02)
	Detail of Fee Submitted	93000.0, 2024-11-19,
	The proposed proprietary name / brand name	Neucalopride 2mg Tablet
	Label Claim	Label Claim: Each film coated tablet contains: Prucalopride succinate equivalent to Prucalopride 2mg (Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 7's-As per SRO
	Shelf Life (Unit)	2 Yearstore at 25C
	For generic drugs (me-too Status)	Notogrity by Seraph pharma

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Seraph Pharmaceutical -M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.-
	The status in reference regulatory authorities	TAKEDA PHARMS USA, Approved in FDA..
	Detail of previous approval	Notogrity 2mg tablet in 331th 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	
644	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(GTP-QWL-GWDX, 2024-11-27)
	Detail of Fee Submitted	93000.0, 9400 2024-10-22, 2026-04-17
	The proposed proprietary name / brand name	MOXIOP EYE DROPS
	Label Claim	Moxifloxacin as HCl 5mg/ml
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	VIGMOX EYE DROP BY NOVARTIS
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	winthrox pharma-plot no K-219/A, phase II, site super highway Karachi-
	The status in reference regulatory authorities	MEHRA APPORVED
	Detail of previous approval	Moxpin opthalmic solution 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	
645	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(HY6-32J-3SDJ, 2024-12-02)

	Detail of Fee Submitted	93000.0, 2024-11-19,
	The proposed proprietary name / brand name	Neuforo 600mg Injection
	Label Claim	COMPOSITION Label Claim: Each vial contain: Ceftaroline Fosamil (with L-Arginine) 600mg (Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Yearstore at 25C
	For generic drugs (me-too Status)	Zinforo Injection 600mg, Pfizer Pvt Limited. (Reg.# 110515)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Seraph Pharmaceutical -M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.-
	The status in reference regulatory authorities	Teflaro 600mg Injecion, Allergan pharma Ireland, FDA Approved Drug.
	Detail of previous approval	Ceffosa Injection 600mg IV/IM, meeting 330th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
646	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Steris Pharmaceuticals Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar (000995)
	Application Form Dy. No / Tracking ID & date of submission	(Q78-HP2-266X, 2024-11-29)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-30, 2024-11-07
	The proposed proprietary name / brand name	CEFAGE 1gm Injection
	Label Claim	Each vial contains: Cefepime hydrochloride eq to Cefepime.....1gm 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 30
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen life Sciences-8-km Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Maxipime 500mg, 1gm & 2gm Injection USFDA Approved
	Detail of previous approval	Minutes of 339th meeting of Registration Board, with brand name of CEFEGEN 1gm 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	
647	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(S5Y-HMM-S3AX, 2024-11-23)
	Detail of Fee Submitted	93000.0, 9400 2024-10-22, 2026-04-17
	The proposed proprietary name / brand name	nepawin eye drops
	Label Claim	Nepafenac 1mg/ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	Nepafen by M/s shaigan pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	winthrox pharma-plot no K-219/A, phase II, site super highway karachi-
	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product/6549/s
	Detail of previous approval	Optinac Ophthalmic Solution 333 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	
648	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(TNH-5DR-53NB, 2024-11-23)
	Detail of Fee Submitted	93000.0, 9400 2024-10-22, 2026-04-17
	The proposed proprietary name / brand name	Tobrawin eye drops
	Label Claim	each ml ophthalmic suspension contains: Tobramycin.....3mg & Dexamethsone 1mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	TOBRADEX SUSPENSION 1mg+3mg/ml Novartis Pharma, Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	winthrox pharma-plot no K-219/A, phase II, site super highway karachi-
	The status in reference regulatory authorities	https://pdf.hres.ca/dpd_pm/00040177.PDF
	Detail of previous approval	M-333 (Tobton-D)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
649	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbelli road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(U64-2GY-DUUA, 2024-11-27)
	Detail of Fee Submitted	93000.0, 2024-09-16,
	The proposed proprietary name / brand name	Omewin Infusion 40mg
	Label Claim	Each vial contains: Omeprazole as Sodium...40mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	Risek Injection 40mg by Getz Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences-8-Km, Chakbeli Road, Rawat-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	Approved in 312th Meeting of Registration Board, Reflex Injection 40mg
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

650	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(WUE-LTD-7EXW, 2024-12-02)
	Detail of Fee Submitted	93000.0, 2024-11-19,
	The proposed proprietary name / brand name	NEUAVI 2.5G INJECTION
	Label Claim	Each vial contain: Cefotaxime pentahydrate eq. to Cefotaxime.....2gm, Avibactam sodium eq to Avibactam.....0.5gm (Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Yearstore at 25C
	For generic drugs (me-too Status)	Zavicefta 2g/0.5g injection Pfizer PVT Limited
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Seraph Pharmaceutical -M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.-
	The status in reference regulatory authorities	Avycaz 2/0.5g injection Allergan Pharma Limited FDA Approved drugs
	Detail of previous approval	Cefavixime 2.0/0.5G Injection IM/IV, Meeting No. 330th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
651	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Focus & Rulz Pharmaceuticals (Pvt) Ltd 44 - Industrial Triangle, Kahuta Road (000628)
	Application Form Dy. No / Tracking ID & date of submission	(XRX-RA9-YMJT, 2024-05-30)
	Detail of Fee Submitted	75000.0, 2024-03-22,
	The proposed proprietary name / brand name	Suno D3 Injection
	Label Claim	Each ampoule contains: Cholecalciferol (Vitamin D3) 5mg (eq. 200,000IU of Vitamin D) Innovator Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30oC
	For generic drugs (me-too Status)	Sunny D Insta Ampoule by Scotmann Pharmaceyticals
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Bio-Labs Pvt. Ltd-Plot #145, Industrial Triangle,Kahuta Road,Islamabad-
	The status in reference regulatory authorities	VITAMINE D3 BON 200 000 U.I. / 1 ml by OUCHARA-RECORDATI LABORATORIES
	Detail of previous approval	Sunray Injection 5mg/mL, 323rd 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.	
652	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Citi pharma ltd 3-km head balloki, Bhai Phero, Kasur. (000512)
	Application Form Dy. No / Tracking ID & date of submission	(9ZV-344-BZD2, 2026-04-18)
	Detail of Fee Submitted	97200, 2026-03-04,
	The proposed proprietary name / brand name	Gabil Tablet 5mg
	Label Claim	Each Film Coated Tablet contains: Mirogabalin besylate eq. to mirogabalin.....5mg (As per Innovator's specs)
	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 YearStore below 30°C.
	For generic drugs (me-too Status)	Miroca Tablet by AGP Pharma
	Pharmacotherapeutic Group of (API)	N02BF03 (Nervous system of Analgesics)
	Name, address of Manufacturing site:	M/s NovaMed Pharmaceuticals (Pvt.) Limited-28-KM Ferozepur Road, Lahore-
	The status in reference regulatory authorities	Tarlige Tablet 5mg by Daiichi sankyo company
	Detail of previous approval	Mirogab Tablet 5mg of M/s NovaMed Pharmaceuticals (Pvt.) Limited
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
653	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Steris Pharmaceuticals Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar (000995)
Application Form Dy. No / Tracking ID & date of submission	(ZXP-9XU-88XP, 2024-11-29)
Detail of Fee Submitted	75000.0, 18000.0 2024-08-30, 2024-11-07
The proposed proprietary name / brand name	CEFAGE 500mg Injection
Label Claim	Each vial contains: Cefepime hydrochloride 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 30
For generic drugs (me-too Status)	Yes
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Biogen life Sciences-8-km Chakbeli Road, Rawat, Rawalpindi-
The status in reference regulatory authorities	USFDA Approved, Maxipime 500mg, 1gm & 2gm Injection
Detail of previous approval	Minutes of 339th meeting of Registration Board; with brand name of CEFEGEN 500mg 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	
654	
Case Category	Contract Manufacturing (Incharge Evaluation Cell)
Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
Application Form Dy. No / Tracking ID & date of submission	(ZYJ-EUH-GA1N, 2024-11-23)
Detail of Fee Submitted	93000.0, 9400 2024-10-22, 2026-04-17
The proposed proprietary name / brand name	Tobralet eye drops
Label Claim	Tobramycin 3mg Loteprednol Etabonate.....5mg Each ml of ophthalmic suspension contains:
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1,s-As per SRO
Shelf Life (Unit)	2 YearBelow 30 °C
For generic drugs (me-too Status)	LOTETOB OPHTHALMIC SUSPENSION 5mg+ 3mg/ml Helix Pharma
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	winthrox pharma-plot no K-219/A, phase II, site super highway Karachi-

	The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/ldr
	Detail of previous approval	M-333 (LOTINON EYE DROPS)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
655	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(J2R-UY3-DBMP, 2025-04-30)
	Detail of Fee Submitted	93000.0, 2025-03-20,
	The proposed proprietary name / brand name	Electrafil 2.5mg Tablets
	Label Claim	Each Film coated Tablet contains: Tadalafil.....2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per DPC-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceutical (Pvt.) Ltd-Plot # 129, Sunder Industrial Estate, Lahore-Pakistan-
	The status in reference regulatory authorities	TADALAFIL TABLET/USFDA
	Detail of previous approval	Procial 2.5mg Tablet, DRB-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	
656	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	(6ME-GSE-NUYW, 2026-04-18)
	Detail of Fee Submitted	97200, 2026-03-12,

	The proposed proprietary name / brand name	Akzith 200mg/5ml Suspension
	Label Claim	Each reconstituted 5ml contains: Azithromycin 200mg (as dihydrate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	15ml-As per SRO
	Shelf Life (Unit)	2 Year Do not store above 30 °C
	For generic drugs (me-too Status)	Zetro 200mg/5ml Oral Suspension (Getz Pharma)
	Pharmacotherapeutic Group of (API)	Antibacterial - Macrolides
	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	Zithromax 200/5ml Oral suspension (USFDA Approved)
	Detail of previous approval	Azysol Suspension 200mg/5ml, 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	
657	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	(YQY-Q3U-M8SR, 2026-04-19)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	Naprox-D Tablet
	Label Claim	Each Film coated tablet contains Diphenhydramine hydrochloride 25 mg Naproxen Sodium 220 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-Free of Cost
	Shelf Life (Unit)	2 Year 15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) LTD-129-Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-348
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
658	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(1P1-E76-DLU1, 2026-04-19)
	Detail of Fee Submitted	97200, 2026-03-15,
	The proposed proprietary name / brand name	Brivapin 50mg Tablet
	Label Claim	Each Film Coated Tablet contains: Brivaracetam - -----50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Brivace 50mg Tablet by M/s Hilton Pharma
	Pharmacotherapeutic Group of (API)	Anti-convulsant
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd.,-Plot No129, Sundar Industrial Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Briviact 50mg Tablet USFDA approved.
	Detail of previous approval	347th meeting of Registration Boar
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
659	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(U96-R5Q-G84U, 2026-04-19)
	Detail of Fee Submitted	97200, 2026-03-15,
	The proposed proprietary name / brand name	Resmepin 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 YearBelow 30°C
	For generic drugs (me-too Status)	Resmet (Resmetirom) 80mg Tablets by : Solaris Life Sciences Private Limited Address: Plot No.

		08, Street No. S-1, RCCI, Industrial Estate, Rawat,(000992)
	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor (THR)-beta agonists.
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd.,-Plot No129, Sundar Industrial Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Rezdiffra (Resmetirom) tablets 80mg USFDA Approved
	Detail of previous approval	347th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
660	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(UBX-2JV-XD9A, 2026-04-19)
	Detail of Fee Submitted	97200, 2026-03-15,
	The proposed proprietary name / brand name	Tapinto IR 75mg Tablet
	Label Claim	Each Film Coated Tablet contains: Tapentadol HCl eq. To Tapentadol -----75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Tapento IR 75mg Tablet Manufacturer Name: M/s Sami Pakistan
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd.,-Plot No129, Sundar Industrial Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Palexia IR 75mg Tablet Manufacturer Name: M/s Grönenthal GmbH, Germany USFDA approved.
	Detail of previous approval	347th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
661	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(XDL-D42-DAA5, 2026-04-19)
	Detail of Fee Submitted	97200, 2026-03-15,
	The proposed proprietary name / brand name	Carboser 500mg/10ml Injection
	Label Claim	Each ml contains: Ferric carboxymaltose Equivalent to Elemental Iron 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	IZER (Ferric carboxymaltose) 500mg/10ml Injection by M/s Pharmasol (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	iron replacement products
	Name, address of Manufacturing site:	M/s Skywin Pharmaceuticals,-Plot No. 01, Al Badar Industrial Estate, Phase-I!. Sheikhpura Road Lahore.-
	The status in reference regulatory authorities	Ferinject 50mg/ml Injection MHRA Approved
	Detail of previous approval	347th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
662	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	GILLMAN PHARMACEUTICALS 41/2-A, PHASE I & II, INDUSTRIAL ESTATE, HATTAR (000683)
	Application Form Dy. No / Tracking ID & date of submission	(Y4T-PR4-NQNP, 2026-04-19)
	Detail of Fee Submitted	97200, 2026-02-12,
	The proposed proprietary name / brand name	Muscorex Injection
	Label Claim	Each 2ml contains: Thiocolchicoside 4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 5's-As per SRO
	Shelf Life (Unit)	2 YearStore at below 30 degree celcius
	For generic drugs (me-too Status)	THIOLAX (SOLACE PHARMA)
	Pharmacotherapeutic Group of (API)	nervous system muscle relaxant, anti-inflammatory, and analgesic drug

	Name, address of Manufacturing site:	Hi-Med Pharmaceuticals-208-C Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	RELIEF4MG/2MLINJECTION (IASIS PHARMA HELLASS.A(137FilisAve,13451 Athens, Greece.)
	Detail of previous approval	Thiomed Injection 4mg/2ml, Meeting No. 351 (Case No. 162)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
663	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(385-GYN-8JVB, 2025-04-30)
	Detail of Fee Submitted	93000.0, 2025-04-14,
	The proposed proprietary name / brand name	Silda 100mg Tablet
	Label Claim	Each film coated tablet contains: Sildenafil citrate Equivalent to Sildenafil.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x5's, 1 x 10's, 2 x-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd. -Plot No. 129, Sundar Industrial Estate Raiwind Road Lahore Pakistan. Phone: 042-111 116 366 -
	The status in reference regulatory authorities	Brand Name: Sildenafil Tablet, USP 100mg, Manufacturer: Rubicon Research Private Limited ambernath, Dist. Thane, 421506, Reference Regulatory Authority: USFDA approved.
	Detail of previous approval	Neogra 25mg Tablet, Approved in Draft Minutes of 345th meeting of Registration Board (19th – 21st Fe
	Evaluation Remarks	
	Applicant has requested to withdraw the application.	
	Decision	
	Rejected	
	The Registration Board acceded to the request of the applicant.	
664	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(5X2-2H6-J4RR, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2025-04-14,
	The proposed proprietary name / brand name	Silda 25mg Tablet
	Label Claim	Each film coated tablet contains: Sildenafil citrate Equivalent to Sildenafil.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x5's, 1 x 10's, 2 x-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd.-Plot # 129, Sunder Industrial Estate, Lahore, Punjab - Pakistan-
	The status in reference regulatory authorities	Brand Name: Sildenafil Tablet, USP 25mg, Manufacturer: Rubicon Research Private Limited ambernath, Dist. Thane, 421506, Reference Regulatory Authority: USFDA approved
	Detail of previous approval	Draft Minutes of 345th meeting of Registration Board (19th – 21st February, 2025)
	Evaluation Remarks	
	Applicant has requested to withdraw the application.	
665	Decision	
	Rejected	
	The Registration Board acceded to the request of the applicant.	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(MX4-EMY-3521, 2025-05-02)
	Detail of Fee Submitted	93000.0, 2025-04-14,
	The proposed proprietary name / brand name	Silda 50mg Tablet
	Label Claim	Each film coated tablet contains: Sildenafil citrate Equivalent to Sildenafil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x5's, 1 x 10's, 2 x-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd. -Plot # 129, Sunder Industrial Estate, Lahore, Punjab - Pakistan.-
	Name & address of API manufacturer	Name: ULTRATECH INDIA LTD., Address: Plot Nos. 24, 25 & 26, New Chemical Zone, M.I.D.C. Taloja, Tal. Panvel, Dist. Raigad410208, Maharashtra, India

	Detail of stability batches of drug product	Attached in Dossier
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Dossier
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Dossier
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Dossier
	The status in reference regulatory authorities	Brand Name: Sildenafil Tablet, USP 50mg, Manufacturer: Rubicon Research Private Limited ambarnath, Dist. Thane, 421506, Reference Regulatory Authority: USFDA approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached in Dossier
	Evaluation Remarks	
	The applicant has requested to withdraw the application.	
	Decision	
	Rejected	
	The Registration Board acceded to the request of the applicant.	
666	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	(R7G-NBV-47VP, 2026-02-18)
	Detail of Fee Submitted	97200, 2026-02-13,
	The proposed proprietary name / brand name	Esimay 500mg/20mg Tablets
	Label Claim	Each modified release tablets contains: Naproxen... 500mg (enteric coated core) Esomeprazole as magnesium trihydrate 20mg (immediate release coat) (As per *Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Manufacturer: Global Pharmaceutical Registration No. 109338 Mfg. License No: 000417
	Pharmacotherapeutic Group of (API)	Dermatological class: NSAID and proton pump inhibitor WHO ATC Code: M01AE02 Naproxen
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	SRA Registration Status: USFDA approved Brand Name: Vimovo delayed release tablet 20/500mg Tablets Manufacturer: Dr. Reddy's Laboratories Limited Route of administration: Oral Dosage Form: Oral Tablets Country of Origin: USA
	Detail of previous approval	APPROVED IN PRVC MD5-JST-R8LA
	Evaluation Remarks	

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

667	Case Category	Any Other (Incharge Evaluation Cell)
	Name, address of Applicant.	Bio-Labs(Pvt) Ltd Plot 145, Industrial Triangle, Kahuta Road (000296)
	Application Form Dy. No / Tracking ID & date of submission	(S8W-RW7-51ZJ, 2025-02-13)
	Detail of Fee Submitted	75000.0, 2025-01-23,
	The proposed proprietary name / brand name	Verdafil
	Label Claim	Each film coated tablet contains: Vardenafil Hydrochloride eq. to Vardenafil.....20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	12's, 20's,24's, 36'-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30°C
	For generic drugs (me-too Status)	N/A.
	Pharmacotherapeutic Group of (API)	Drugs used in erectile dysfunction ATC code: G04BE09.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Centurey Pharmaceuticals limited
	Detail of stability batches of drug product	03 batches having batch size of 1500 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of DHL receipt mentioning airway bill No. 7157313157 along with form 3 and Form 7. However, neither any license to import nor any clearance certificate is provided by the firm.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against innovator product i.e. LEVITRA 20 MG Tablet, B. No. BXJ93C9, Mfg. date 02/23. Both innovator product and applied product have shown similar release pattern in all the three mediums of CDP and values of F2 are also in acceptable range.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-B is submitted. Accelerated 06 months and real time for 60 months.
	The status in reference regulatory authorities	LEVITRA® (Vardenafil HCl) tablets, USFDA approved. Vardenafil 10 mg & 20mg tablets, MHRA approved.
	GMP status of the firm	Firm has submitted copy of GMP Certificate No. No. F.3-19/2019-Addl. Dir. (QA<-I)-77 dated 28-12-2023 issued on the basis of inspection conducted on 09-10-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-12/98-Lic (Vol-II) dated 24-03-2007 mentioning Tablet

(General) section.

Evaluation Remarks

The firm has requested to withdraw this application as follows:

Decision

Rejected

The Registration Board acceded to the request of the applicant.

668	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	(VAS-5PE-5R77, 2026-02-18)
	Detail of Fee Submitted	97200, 2026-02-13,
	The proposed proprietary name / brand name	TOFIX 5MG TABLET
	Label Claim	Each film coated tablet contains: Tofacitinib citrate equivalent to Tofacitinib 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Tofcib 5mg Tablet Seraph Pharmaceutical
	Pharmacotherapeutic Group of (API)	Immunosuppressants, Janus-associated kinase (JAK) inhibitor
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	Brand Name: XELJANZ 5mg Tablets Registration holder: RRA Pfizer Limited Ramsgate Road SandwichKent CT13 9NJ United Kingdom MHRA Approved Drug.
	Detail of previous approval	7QH-63V-13HH (APPROVE IN PRVC)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
669	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	(9MZ-BRU-TVL4, 2026-04-20)
	Detail of Fee Submitted	97200, 2026-03-12,

	The proposed proprietary name / brand name	Vodyn Plus
	Label Claim	Each film coated tablet contains: Aspirin.....100mg (as Enteric coated core) Vonoprazan as Fumarate.....10mg (as immediate release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-De-Controlled,2x10's-De-Controlled,2x7's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Asvon 100mg+10mg Tablet by Swiss Pharma (Reg.no.120274)
	Pharmacotherapeutic Group of (API)	NSAID/P-CAB
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt.) Ltd.-Plot no. 129, Sundar Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Cabpirin 100mg/10mg Tablet by Takeda Pharma, Approved in PMDA-Japan
	Detail of previous approval	Vozan-AS 100/10mg Tablet, Meeting minute 340th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
670	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Caliph Pharmaceuticals (Pvt) Ltd. Plot 17, Special Industrial Zone (EPZ), Risalpur, KPK (000748)
	Application Form Dy. No / Tracking ID & date of submission	(9UN-EJD-D32J, 2026-04-20)
	Detail of Fee Submitted	97200, 2026-03-16,
	The proposed proprietary name / brand name	OLPACAL EYE DROPS
	Label Claim	Each ml contains: Olopatadine as HCl 2mg
	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)	Eyepat Drops by Hansel Pharmaceuticals Pvt Ltd
	Pharmacotherapeutic Group of (API)	Data already approved in 339 MoM
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, S.I.T.E., Super Highway, Karachi -PAKISTAN.-
	The status in reference regulatory authorities	FDA Approved
	Detail of previous approval	Olopton Drops in 339 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	
671	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	(S1Y-2EQ-1ZJ9, 2026-04-20)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	Avanor 50mg Tablets
	Label Claim	Each tablet contains: Avanafil..... 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Medizan Laboratoreis 351th meeting Avala 50Tablets)
	Pharmacotherapeutic Group of (API)	Avanafil belongs to the pharmacotherapeutic group of Urologicals; Drugs used in erectile dysfunction. Specifically, it is a phosphodiesterase type 5 (PDE5) inhibitor. Its mechanism of action involves inhibiting PDE5, which is an enzyme that plays a role in the development of erections
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	STENDRA™ (avanafil) tablets, for oral use Tablets: 50 mg, 100 mg, 200 mg Initial U.S. Approval: 2012 Company: Manufactured for VIVUS, Inc. Mountain View, CA 94040 Manufactured in Osaka Japan Study Reference: https://www.accessdata.fda.gov/drugsatfda_docs/labeling/2012/021222Orig1s01.pdf https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/201222Orig1s01.pdf https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/201222Orig1s01.pdf https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/201222Orig1s01.pdf
	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	

672	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	(DSM-3NX-JT75, 2026-04-20)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	AVANOR 100mg Tablets
	Label Claim	Each tablet contains: Avanafil 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Medizan Laboratoreis 351th meeting
	Pharmacotherapeutic Group of (API)	Avanafil belongs to the pharmacotherapeutic group of Urologicals; Drugs used in erectile dysfunction. Specifically, it is a phosphodiesterase type 5 (PDE5) inhibitor. Its mechanism of action involves inhibiting PDE5, which is an enzyme that plays a role in the development of erections
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	STENDRA™ (avanafil) tablets, for oral use Tablets: 50 mg, 100 mg, 200 mg Initial U.S. Approval: 2012 Company: Manufactured for VIVUS, Inc. Mountain View, CA 94040 Manufactured in Osaka Japan Study Reference: https://www.accessdata.fda.gov/drugsatfda_docs/labeling/2012/021221Orig1s01.pdf https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/212211Orig1s01.pdf https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/212211Orig1s01.pdf https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/212211Orig1s01.pdf
	Detail of previous approval	351th meeting
673	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
673	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	(4TJ-897-T8JH, 2026-04-20)
	Detail of Fee Submitted	97200, 2026-03-12,

	The proposed proprietary name / brand name	Lizonor 100mg Tablets
	Label Claim	Each film-coated tablet contains: LINZAGOLIX. Choline eq. to LINZAGOLIX. 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Medizan Laboratoreis 351th meeting
	Pharmacotherapeutic Group of (API)	Belongs to hypothalamic hormones, specifically non-peptide GnRH receptor antagonists used as anti-gonadotropins
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	Ysely 100 mg film-coated tablets, for oral use Ysely 200 mg film-coated tablets, for oral use LINZAGOLIX. (as LINZAGOLIX. choline) Approval: MHRA in January, 2025 Marketing Authorizations: Theramex Ireland Limited (PLGB 49876/0023-0024). Study Reference: https://www.ema.europa.eu/en/documents/assessment-report/ysely-epar-public-assessment-report_en.pdf https://www.ema.europa.eu/en/medicines/human/E https://mhraproducts4853.blob.core.windows.net/c
	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	
674	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	(XP3-2BQ-LX6E, 2026-04-20)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	Lizonor 200mg
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Medizan Laboratoreis 351th meeting
	Pharmacotherapeutic Group of (API)	Belongs to hypothalamic hormones, specifically non-peptide GnRH receptor antagonists used as anti-gonadotropins

	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	Ysely 100 mg film-coated tablets, for oral use Ysely 200 mg film-coated tablets, for oral use Linzagolix (as linzagolix choline) Approval: MHRA in January, 2025 Marketing Authorizations: Theramex Ireland Limited (PLGB 49876/0023-0024). Study Reference: https://www.ema.europa.eu/en/documents/assessment-report/ysely-epar-public-assessment-report_en.pdf https://www.ema.europa.eu/en/medicines/human/E https://mhraproducts4853.blob.core.windows.net/c
	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.	
675	Decision	
	Approved	
	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	(R8Z-ULY-AQNN, 2026-04-20)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	Vardanor 5mg
	Label Claim	Each film-coated 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 Year30C
	For generic drugs (me-too Status)	Medizan Laboratoreis 351th meeting
	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-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	LEVITRA® (Vardenafil HCl) tablets, for oral use Tablets: 2.5 mg, 5 mg, 10 mg, 20 mg Initial U.S. Approval: 2003 Company: Manufactured By: Bayer Healthcare Bayer Pharmaceutical Corporation 400 Morgan Lane, West Haven CT 06516 Made in Germany Marketed by: GSK GlaxoSmithKline Research Triangle Park NC

		27709 https://www.accessdata.fda.gov/drugsatfda_docs/n400_Levitra.cfm https://www.accessdata.fda.gov/drugsatfda_docs/la https://www.accessdata.fda.gov/drugsatfda_docs/la
	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	
676	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	(XP9-ME4-PTAM, 2026-04-20)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	Vardanor 10 mg
	Label Claim	Each film-coated 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 Year30C
	For generic drugs (me-too Status)	Medizan Laboratoreis 351th meeting
	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-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	LEVITRA® (Vardenafil HCl) tablets, for oral use Tablets: 2.5 mg, 5 mg, 10 mg, 20 mg Initial U.S. Approval: 2003 Company: Manufactured By: Bayer Healthcare Bayer Pharmaceutical Corporation 400 Morgan Lane, West Haven CT 06516 Made in Germany Marketed by: GSK GlaxoSmithKline Research Triangle Park NC 27709 https://www.accessdata.fda.gov/drugsatfda_docs/n400_Levitra.cfm https://www.accessdata.fda.gov/drugsatfda_docs/la https://www.accessdata.fda.gov/drugsatfda_docs/la
	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

677	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	(5LA-38D-HR2E, 2026-04-20)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	Vardanor 20 mg
	Label Claim	Each film-coated tablet contains: Vardenafil Hydrochloride eq. to Vardenafil 20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	as per sro-Free of Cost
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Medizan Laboratoreis 351th meeting
	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-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	LEVITRA® (Vardenafil HCl) tablets, for oral use Tablets: 2.5 mg, 5 mg, 10 mg, 20 mg Initial U.S. Approval: 2003 Company: Manufactured By: Bayer Healthcare Bayer Pharmaceutical Corporation 400 Morgan Lane, West Haven CT 06516 Made in Germany Marketed by: GSK GlaxoSmithKline Research Triangle Park NC 27709 https://www.accessdata.fda.gov/drugsatfda_docs/n400_Levitra.cfm https://www.accessdata.fda.gov/drugsatfda_docs/l400_Levitra.cfm https://www.accessdata.fda.gov/drugsatfda_docs/nda/021-104-Orig1s1/Levitra.pdf
	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	
678	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Caliph Pharmaceuticals (Pvt) Ltd. Plot 17, Special Industrial Zone (EPZ), Risalpur, KPK (000748)
	Application Form Dy. No / Tracking ID & date of submission	(8PB-6GG-1RPM, 2026-04-20)
	Detail of Fee Submitted	97200, 2026-03-16,
	The proposed proprietary name / brand name	RAMOXIN EYE DROPS
	Label Claim	Each ml contains: Moxifloxacin as HCl 5mg
	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)	Vigamox Eye drops by Novartis pharma
	Pharmacotherapeutic Group of (API)	Data already approved in 339 MoM
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, S.I.T.E., Super Highway, Karachi -PAKISTAN.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Moxon Eye Drops in 339 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	
679	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd. Kalalwala Stop, 20 Km Lahore-Jaranwala Road, District Sheikhpura (000019)
	Application Form Dy. No / Tracking ID & date of submission	(RNY-374-5MSL, 2026-04-20)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	Lizolix 100mg Tablets
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,100's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,50's-As per SRO,84's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Endoflex Tablet 100mg Registration No: 133211 Company Name: Genome Pharmaceuticals (Pvt.) Ltd,

	Pharmacotherapeutic Group of (API)	Gonadotrophin-releasing hormone (GnRH) receptor antagonist,
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt) Ltd.-Plot No 313 Industrial Triangle Kahuta Road Islamabad -
	The status in reference regulatory authorities	Ysely 100 mg film-coated tablets, for oral use Ysely 200 mg film-coated tablets, for oral use Linzagolix (as linzagolix choline) Approval: MHRA in January, 2025 Marketing Authorizations: Theramex Ireland Limited (PLGB 49876/0023-0024)
	Detail of previous approval	Lingolix 100mg Tablets 351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
680	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd. Kalalwala Stop, 20 Km Lahore-Jaranwala Road, District Sheikhpura (000019)
	Application Form Dy. No / Tracking ID & date of submission	(DWL-NBE-NVXU, 2026-04-20)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	Lizolix 200mg Tablets
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix 200m
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,100's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,50's-As per SRO,84's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Endoflex Tablet 200mg Registration No: 133212 Company Name: Genome Pharmaceuticals (Pvt.) Ltd,
	Pharmacotherapeutic Group of (API)	Gonadotrophin-releasing hormone (GnRH) receptor antagonist,
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt) Ltd.-Plot No 313 Industrial Triangle Kahuta Road Islamabad -
	The status in reference regulatory authorities	Ysely 100 mg film-coated tablets, for oral use Ysely 200 mg film-coated tablets, for oral use Linzagolix (as linzagolix choline) Approval: MHRA in January, 2025 Marketing Authorizations: Theramex Ireland Limited (PLGB 49876/0023-0024)
	Detail of previous approval	Lingolix 200mg Tablets 351 DRB Meeting
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
681	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(M8Q-J2Z-YDAM, 2026-04-20)
	Detail of Fee Submitted	97200, 2026-03-11,
	The proposed proprietary name / brand name	ENDORM INJECTION
	Label Claim	Each 1ml Contains: Cholecalciferol (Vitamin D3) 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 X 1'S 1ml X 5'S-De-Controlled
	Shelf Life (Unit)	2 Yearstore at room temperature
	For generic drugs (me-too Status)	NEW-D
	Pharmacotherapeutic Group of (API)	VITAMIN D ANALOG
	Name, address of Manufacturing site:	HI-MED PHARMACEUTICALS-208-C SUNDER INDUSTRIAL ESTATE LAHORE-
	The status in reference regulatory authorities	ANSM FRANCE
	Detail of previous approval	VTD 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	
682	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	(J7L-P91-QAS2, 2026-04-20)
	Detail of Fee Submitted	97200, 216300 2026-02-04, 2026-04-20
	The proposed proprietary name / brand name	Dutasin Capsule
	Label Claim	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) 0.5 mg Tamsulosin

		hydrochloride (as modified release pellets) 0.4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Brand Name: Registration holder: Registration Number: Maxflow-D Capsule CCL Pharmaceuticals (Pvt.) Ltd. 091571
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic group: WHOATC Code: Alpha-adrenoreceptor antagonists G04CA52
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi -
	The status in reference regulatory authorities	Brand Name Marketing Authorization holder: Regulatory Authority: Dutasteride/Tamsulosin hydrochloride 0.5 mg / 0.4 mg hard capsules Milpharm Limited Medicines and Healthcare products Regulatory Agency (MHRA)
	Detail of previous approval	335th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
683	Case Category	Contract Manufacturing (Iqra Aftab)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(68D-HNY-V9VP, 2024-11-14)
	Detail of Fee Submitted	93000.0, 2024-10-24,
	The proposed proprietary name / brand name	Saltiflu DPI Capsule
	Label Claim	Each dry powder inhaler capsule contains Fluticasone Propionate ----- 100mcg Salmeterol Xinafoate eq to Salmeterol base 50mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7's,10's,14's,20's,2-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	Seretide Disku 100mcg/50mcg DPI Capsule by Glaxo Smith Kline (GSK)
	Pharmacotherapeutic Group of (API)	Cross-referred
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	ADVAIR DISKUS 100mcg/50mcg by Glaxo Smith Kline

	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected "No" in data already approved. Later on, they cross referred to already approved data of M-354 of M/s. Genix Pharma (Pvt) Ltd "without submission of pre-registration fee". 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 by the Board as an application of cross-reference, already approved data on Form 5F. Applicant has submitted a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification.	
	Decision	
	Approved	
	The registration letter will be issued upon submission of pre-registration variation fee.	
684	Case Category	Contract Manufacturing (Iqra Aftab)
	Name, address of Applicant.	OBS Pharma (Pvt) Ltd 108 Kotlakhpat Industrial Estate, Lahore 54760 Pakistan (000243)
	Application Form Dy. No / Tracking ID & date of submission	(LU5-WZZ-PHRQ, 2024-11-01)
	Detail of Fee Submitted	93000.0, 9400 2024-10-31, 2026-04-17
	The proposed proprietary name / brand name	Posaconazole 40mg/ml Or al Suspension
	Label Claim	Each ml of oral suspension contains: Posaconazole.....40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30 degree
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals pvt ltd-Plot No 129 Sundar industrial estate raiwind road lahore-
	The status in reference regulatory authorities	Posaconazole 40mg/ml oral suspension M/S Thornton & Ross Ltd. (trading as STADA)Linthwaite,Huddersfield,HD7 5QH, UK
	Detail of previous approval	M-353
	Evaluation Remarks	
	The firm initially selected "No" in data already approved. Later on, it submitted pre-registration fee and cross referred already approved data of M-353 of M/s Wimits Pharmaceuticals. 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 by the Board as an application of cross-reference, already approved data on Form 5F. Applicant has submitted a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification.	
	Decision	
	Approved	
685	Case Category	Contract Manufacturing (Iqra Aftab)
	Name, address of Applicant.	OBS Pharma (Pvt) Ltd 108 Kotlakhpat Industrial Estate, Lahore 54760 Pakistan (000243)

	Application Form Dy. No / Tracking ID & date of submission	(19U-N2L-Z9LX, 2024-10-31)
	Detail of Fee Submitted	93000.0, 9400 2024-10-31, 2026-04-17
	The proposed proprietary name / brand name	Posaconazole 100mg DR Tablet
	Label Claim	Each Delayed-Release Tablet contains: Posaconazole.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30 degree
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals pvt ltd-Plot No 129 Sundar industrial estate raiwind road lahore-
	The status in reference regulatory authorities	Posaconazole 100mg DR Tablet Posaconazole 100mg DR Tablet USFDA
	Detail of previous approval	M-353
	Evaluation Remarks	
	The firm initially selected "No" in data already approved. Later on, it submitted pre-registration fee and cross referred already approved data of M-353 of M/s Wimits Pharmaceuticals. 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. Applicant submitted a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification.	
686	Decision	
	Approved	
	Case Category	Contract Manufacturing (Iqra Aftab)
	Name, address of Applicant.	M/s Daneen Pharma (Pvt) Ltd Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, (000688)
	Application Form Dy. No / Tracking ID & date of submission	(XB5-MMU-HQ1W, 2024-11-13)
	Detail of Fee Submitted	93000.0, 2024-10-24,
	The proposed proprietary name / brand name	Saltiflu DPI Capsule
	Label Claim	Each dry powder inhaler capsule contains Fluticasone Propionate ----- 500mcg Salmeterol Xinafoate eq to Salmeterol base 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7's,10's,14's,20's,2-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	Seretide Disku 500mcg/50mcg DPI Capsule by Glaxo Smith Kline (GSK)
	Pharmacotherapeutic Group of (API)	Cross referenced product
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-

	The status in reference regulatory authorities	ADVAIR DISKUS 500mcg/50mcg by Glaxo Smith Kline
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected "No" in data already approved. Later on, they cross referred to already approved data of M-354 of M/s Genix without submission of pre-registration variation fee. 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 by the Board as an application of cross-reference, already approved data on Form 5F. Applicant has submitted a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification.	
	Decision	
	Approved	
	Registration letter will be issued on submission of pre-registration variation fee.	
687	Case Category	New Section (Iqra Aftab)
	Name, address of Applicant.	Oncogen Pharma (Pvt) Limited WH-26 & 27-A3 , Korangi Creek Industrial Park (KCIP) (000960)
	Application Form Dy. No / Tracking ID & date of submission	(ELW-V4W-977H, 2026-01-05)
	Detail of Fee Submitted	38700, 2025-09-09,
	The proposed proprietary name / brand name	Cisnova concentrate for solution for infusion 50mg/50ml
	Label Claim	Each 50ml contains: Cisplatin.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 vial-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 25 °C. Do not refrigerate or freeze. Protect from heat & light
	For generic drugs (me-too Status)	Cisplasol Injection 50mg/50ml
	Pharmacotherapeutic Group of (API)	Platinum containing anti-neoplastic agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Boyuan Pharmaceutical Co., Ltd. Address No. 12, Taixing East Street, Jibei Economic Development Zone, Jiyang District, Jinan City, Shandong Province
	Detail of stability batches of drug product	Stability studies of 03 batches i.e. P09.NP.ST.001, P09.NP.ST.002 & P09.NP.ST.003 is enclosed.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Final Clearance Certificate dated: 18-03-2025. Batch No: 250201CI
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cisplatin Injection 50mg/50mL to the reference product Cisplasol Injection 50mg/50mL
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of 24 months have been submitted.230801030 230802030,230803030, 30 °C ± 2 °C; relative humidity: 75% ± 5% for long term studies 40 °C ± 2 °C; relative humidity: 75% ± 5% for accelerated studies
	The status in reference regulatory authorities	MHRA Approved,Hospira UK Limited Walton Oaks Walton-On-The-Hill Dorking Road Tadworth Surrey KT20 7NS UK

	GMP status of the firm	GMP certificate is based on evaluation conducted on 07th December, 2023. Validity: 3 years.
	Evidence of approval of manufacturing facility	Liquid injectable(with lyophilizer facility) (Oncology) approved on 02-11-2023
	Evaluation Remarks	
	In use: Following dilution in 0.9% sodium chloride injection to a final concentration of 0.15 mg/mL, chemical in-use stability has been demonstrated for up to 14 days at 25°C when stored in non-PVC infusion bags, and for 24 hours when stored at 25°C protected from light when prepared in PVC infusion bags.	
	Decision	
	Approved	
	The registration letter will be issued upon submission of in-use stability study data demonstrating stability after dilution in 0.9% sodium chloride injection to a final concentration of 0.15 mg/mL, for preparations stored in both non-PVC and PVC infusion bags.	
688	Case Category	Import (Muhammad Sarfraz Nawaz)
	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	(1J9-EZ8-745X, 2024-12-06)
	Detail of Fee Submitted	300000.0, 2024-11-29,
	The proposed proprietary name / brand name	ELTRO TABLETS 25 MG
	Label Claim	Each Film Coated Tablet Contains: Eltrombopag Olamine Eq. to Eltrombopag 25 mg (Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4x7's Blister Pack-As per SRO
	Shelf Life (Unit)	24 Monthstore below 30 degree centigrade
	For generic drugs (me-too Status)	Revolade Tablets 25 mg (Eltrombopag 25 mg) Registration # 084158
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Grand Pharmaceutical (China) Co., Ltd. - Production address: No.11, Huanhu Middle Road, Jinyin Lake Ecological Park, Dongxihu District, Wuhan, Hubei Province, China Postal code: 430040 -China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Grand Pharmaceutical (China) Co., Ltd. , Production address: No.11, Huanhu Middle Road, Jinyin Lake Ecological Park, Dongxihu District, Wuhan, Hubei Province, China Postal code: 430040 , 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	Revolade 25 mg tablets by Novartis UK, MHRA Approved
	Evaluation Remarks	

	Decision	
	Approved	
	Approved as per current import policy and firm shall submit original legalized CoPP/GMP+FSC along with product specific letter of authorization before issuance of letter.	
689	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Karim Traders Cutchi gali no 1, marriott road karachi (616)
	Application Form Dy. No / Tracking ID & date of submission	(3SA-UAZ-N2VH, 2024-12-24)
	Detail of Fee Submitted	300000.0, 2024-12-20,
	The proposed proprietary name / brand name	Sold with generic name
	Label Claim	Each ampoule contains 5ml of Sterile Water for injection BP.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ampoules box-Controlled
	Shelf Life (Unit)	3 YearStore below 30°C. Use once only and discard any remaining portion.
	For generic drugs (me-too Status)	Sterile Water for Injection 5ml Marketed by Qasim Traders Karachi Manufactured by Wuhan Grand Pharmaceutical Co Ltd China
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Huazhong Pharmaceutical Co., Ltd.-No.118 Xian Shan Road., Xiang Yang City, Hubei, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Ningbo Sinofin Pharmaceutical Co., Ltd, 9-11 West Zhongshan Road, Ningbo, China , China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	MHRA Approved
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved as per current import policy and firm shall submit original legalized CoPP/GMP+FSC along with product specific letter of authorization before issuance of letter.	
690	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Karim Traders Cutchi gali no 1, marriott road karachi (616)
	Application Form Dy. No / Tracking ID & date of submission	(6ZP-RNE-U97E, 2024-09-30)
	Detail of Fee Submitted	300000.0, 2024-09-06,
	The proposed proprietary name / brand name	Sold with generic name
	Label Claim	Each capsule contains indomethacin 25mg.

	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10 Capsule/Blister a-Controlled,1000 Capsule Tin -Controlled
	Shelf Life (Unit)	3 YearStore below 30°C. Protect from light. Keep out of reach of children.
	For generic drugs (me-too Status)	Indocin Capsule
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Jinzhou Jiuyang Pharmaceutical Co., Ltd.-No.6, Road three Street jingang Economic & Technological Development Zone, City Jinzhou, province Liaoning, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Ningbo Sinofin Pharmaceutical Co., Ltd, 9-11 West Zhongshan Road, Ningbo, China , China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	MHRA Approved
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved as per current import policy and firm shall submit original legalized CoPP/GMP+FSC along with product specific letter of authorization before issuance of letter.	
691	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Karim Traders Cutchi gali no 1, marriott road karachi (616)
	Application Form Dy. No / Tracking ID & date of submission	(E1Q-YEY-4WDJ, 2024-10-08)
	Detail of Fee Submitted	300000.0, 2024-07-12,
	The proposed proprietary name / brand name	Sold with generic name
	Label Claim	Dexamethasone Sodium Phosphate Injection 4mg/1ml Each 1ml ampoule contains 4.37mg Dexamethasone sodium phosphate equivalent to 4mg of dexamethasone phosphate. USP
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5Ampoules/Tray, 5Tra-Controlled
	Shelf Life (Unit)	3 YearKeep container in the outer carton. Do not freeze. Store below 25° C. Any unused portion should be discarded immediately after use
	For generic drugs (me-too Status)	DECADRON Dexamethasone Sodium Phosphate injection USP 4mg/1ml From Manufacturer, Searle Pakistan Limited.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Huazhong Pharmaceutical Co., Ltd.-No.118 Xian Shan Road., Xiang Yang City, Hubei, China-

		China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Ningbo Sinofin Pharmaceutical Co., Ltd, 9-11 West Zhongshan Road, Ningbo, China , China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	TGA Approved
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	Approved as per current import policy and firm shall submit original legalized CoPP/GMP+FSC along with product specific letter of authorization before issuance of letter.	
692	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Karim Traders Cutchi gali no 1, marriott road karachi (616)
	Application Form Dy. No / Tracking ID & date of submission	(G11-MUL-3PSN, 2024-10-03)
	Detail of Fee Submitted	300000.0, 2024-09-26,
	The proposed proprietary name / brand name	Sold with generic name
	Label Claim	Oxytetracycline Hydrochloride Capsule 250mg Each capsule contains oxytetracycline hydrochloride 269.8 mg equivalent to 250mg Oxytetracycline
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10 Capsule/Blister a-Controlled,1000 Capsule Tin-Controlled
	Shelf Life (Unit)	3 YearStore below 30°C. Protect from light. Keep out of reach of children.
	For generic drugs (me-too Status)	Oxytetracycline Hydrochloride Capsule 250mg by Amros Pharmaceutical
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Jinzhou Jiuyang Pharmaceutical Co., Ltd.-No.6, Road three Street jingang Economic & Technological Development Zone, City Jinzhou, province Liaoning, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Ningbo Sinofin Pharmaceutical Co., Ltd, 9-11 West Zhongshan Road, Ningbo, China , China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	MHRA Approved
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	

	Decision	
	Approved	
	Approved as per current import policy and firm shall submit original legalized CoPP/GMP+FSC along with product specific letter of authorization before issuance of letter.	
693	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	punjnad pharma PVT LTD 35-km shamy bhattian multan road lahore (053520066059717D)
	Application Form Dy. No / Tracking ID & date of submission	(NDV-3UN-VPVW, 2025-03-13)
	Detail of Fee Submitted	300000.0, 2025-02-26,
	The proposed proprietary name / brand name	FIPROES CAT SPOT-ON SOLUTION
	Label Claim	Fiproes Cat Spot-on Solution is used in cats for; treatment and prevention of flea and/or tick infestations. It is used as part of the treatment for controlling Flea Allergic Dermatitis (FAD), for the treatment and prevention of flea (Ctenocephalides spp.) and tick (Ixodes ricinus, Dermacentor variabilis, Rhipicephalus sanguineus, Rhipicephalus turanicus) infestations, and for the elimination of biting lice (Felicola subrostratus). Fiproes Cat Spot-on Solution exhibits immediate insecticidal effectiveness against adult fleas for up to 8 weeks. It prevents the laying of eggs (ovicidal activity) and inhibits the development of eggs into adults, thus preventing flea multiplication for 6 weeks after application. It also provides immediate and persistent acaricidal activity for 5 weeks after application.
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	3x0.5ml-De-Controlled
	Shelf Life (Unit)	3 YearSTORE BELOW 25 DEGREE CENTIFRADE
	For generic drugs (me-too Status)	NOT AVAILABLE
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	TEKNOVET ILAC SAN. VE TIC. A.S.-C.O.S.B. GAZI OSMAN PASA MAHALLESİ 18. SOKAK NO:3 59500 CERKEZKOY/ TEKIRDAG/TURKEY-Turkey
	Name, address of Marketing Authorization Holder:	PUNJNAD PHARMA (PVT) LIMITED, 35-KM, MULTAN ROAD, SHAMKEY BHATTIAN LAHORE, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	

	Approved	
	Approved as per current import policy and firm shall submit original legalized CoPP/GMP+FSC.	
694	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	OPTIMUS LABORATORIES (PVT.) LTD. 259 F1 Block Wapda Town (001010)
	Application Form Dy. No / Tracking ID & date of submission	(88V-DHZ-WN6P, 2026-01-28)
	Detail of Fee Submitted	38700, 2025-12-16,
	The proposed proprietary name / brand name	OPTIBREX-D Ophthalmic Suspension
	Label Claim	Each ml of Suspension Contains: Dexamethasone....1.0mg Tobramycin..... 3.0mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Optibrex-D by Winthrox (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Dexamethasone: corticosteroid Tobramycin: Aminoglycoside Antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Livzon group Fuzhou Fuxing Pharmaceutical CO.LTD. NO.8 Nangang Road, Jiangyin Industrial Concentration Zone Fuqing Fuzhou City Fujian Province P.R China 350309 China,Zhejiang Xianju Pharmaceutical Co., Ltd. (Xianju) 1 Xianyao RoadXianju, Zhejiang China 317300
	Detail of stability batches of drug product	600 bottles of each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan API taken without timely intimation to DRAP, hence may be verified accordingly.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted PE data against Optibrex-D Ophthalmic Suspension of Ms Winthrox Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are according to zone IV A.
	The status in reference regulatory authorities	FDA approved
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Attached.
695	Evaluation Remarks	
	The firm has borrowed APIs without timely intimating DRAP, hence may be verified accordingly.	
	Decision	
	Approved	
	subject to verification of loan letter.	
695	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)

	Application Form Dy. No / Tracking ID & date of submission	(8TH-JXW-B2TH, 2026-04-14)
	Detail of Fee Submitted	38700, 2026-04-06,
	The proposed proprietary name / brand name	NEOXYFLOR F.R.
	Label Claim	Oxytetracycline HCl 300 mg, Neomycin Sulphate 150 mg, Florfenicol 100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg HDPE JAR-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	(128568) Neofol Oral Powder of M/s. Alina Combine Pharmaceuticals Pvt. Ltd. Karachi.
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	The firm has also demanded following pack sizes: 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 10Kg, 25Kg	
696	Decision	
	Approved	
	upto 1Kg pack size.	
	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(97G-VH5-V6P9, 2026-03-25)
	Detail of Fee Submitted	38700, 2026-03-24,
	The proposed proprietary name / brand name	TILMICO F.R.
	Label Claim	Each ml contains: Tilmicosin as Phosphate..... 250 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 litre HDPE Bottle-De-Controlled
	Shelf Life (Unit)	2 Year(s)Belo 30 degree
	For generic drugs (me-too Status)	128391 Tilfarsin Solution of M/s. Izfaar Pharmaceutical (Pvt) Limited. Lahore.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	The firm has also demanded following pack sizes: 100ml, 250ml, 500ml, 1L, 5L	
	Decision	
	Approved	
	upto 1L pack size.	

697	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(RNG-UG7-VS1Q, 2026-03-25)
	Detail of Fee Submitted	38700, 2026-03-24,
	The proposed proprietary name / brand name	DOXY F.R.
	Label Claim	Each 100gram contains: Doxycycline Hyclate.....50 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg HDPE JAR-De-Controlled
	Shelf Life (Unit)	2 Year(s)Belo 30 degree
	For generic drugs (me-too Status)	122238 DOXY ONE ORAL POWDER of Ms ONE HEALTH PHARMA, KOTRI, SINDH.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	The firm has also applied for following pack sizes: 100gm, 500gm, 1Kg, 2Kg, 3Kg and 5Kg	
	Decision	
	Approved	
	upto 1Kg pack size.	
698	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(ADP-4EQ-7W97, 2026-04-06)
	Detail of Fee Submitted	38700, 2026-04-06,
	The proposed proprietary name / brand name	LZYO F.R.
	Label Claim	Each gram contains: Lysozyme.....220mg Vitamin E 50 SD..... 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg HDPE JAR-De-Controlled
	Shelf Life (Unit)	2 Year(s)Belo 30 degree
	For generic drugs (me-too Status)	122733 ONEGIZER ORAL POWDER of M/S. ONE HEALTH PHARMA, KOTRI, SINDH.
	Pharmacotherapeutic Group of (API)	vitamin/ enzyme
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	The firm has also demanded following pack sizes: 100gm, 250gm, 500gm, 1Kg and 5Kg	
	Decision	

	Approved	
	upto 1Kg pack size.	
699	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(BB9-52B-ZW9J, 2026-03-27)
	Detail of Fee Submitted	38700, 2026-03-26,
	The proposed proprietary name / brand name	LINCO F.R. 4.4%
	Label Claim	Lincomycin HCl 4.4%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg HDPE JAR-De-Controlled
	Shelf Life (Unit)	2 Year(s)Belo 30 degree
	For generic drugs (me-too Status)	121955 LINCOFARM TR ORAL POWDER of M/S. ZS BIOTECH, LAHORE.
	Pharmacotherapeutic Group of (API)	Antimicrobial
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	The firm has also demanded following pack size: 100gm, 500gm, 1Kg and 5Kg	
	Decision	
	Approved	
	upto 1Kg pack size.	
700	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(DBL-ARX-S4W2, 2026-04-03)
	Detail of Fee Submitted	38700, 2026-04-02,
	The proposed proprietary name / brand name	FLUMECOL-F.R.
	Label Claim	Each gram contains: Flumequine..... 100 mg Colistin Sulphate..... 400,000 IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg HDPE JAR-De-Controlled
	Shelf Life (Unit)	2 Year(s)Belo 30 degree
	For generic drugs (me-too Status)	Aviquil plus powder of Ms UM Enterprises Korangi Industrial Area Karachi
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Submitted

	Evaluation Remarks	
	The firm has demanded following pack sizes: 100gm, 500gm, 1Kg, 2Kg, 3Kg and 5Kg	
	Decision	
	Approved	
	upto 1Kg pack size.	
701	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(GA8-PWW-M6P2, 2026-03-27)
	Detail of Fee Submitted	38700, 2026-03-27,
	The proposed proprietary name / brand name	FENICOL F.R.
	Label Claim	Each ml contains: Florfenicol.....250 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 litre HDPE Bottle-De-Controlled
	Shelf Life (Unit)	2 Year(s)Belo 30 degree
	For generic drugs (me-too Status)	122863 PANFENICOL 25 ORAL LIQUID of M/S. PRIX PHARMACEUTICA, LAHORE.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	The firm has demanded following pack sizes: 30ml, 100ml, 120ml, 250ml, 500ml, 1L	
	Decision	
	Approved	
	upto 1L pack size.	
702	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(JVP-3PP-18RS, 2026-03-27)
	Detail of Fee Submitted	38700, 2026-03-26,
	The proposed proprietary name / brand name	NEOCIN F.R. 72%
	Label Claim	Each gram contains: Neomycin Sulphate.....720mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg HDPE JAR-De-Controlled
	Shelf Life (Unit)	2 Year(s)Belo 30 degree
	For generic drugs (me-too Status)	125746 Eter-Brocin 72% Powder of Ms Eterna Pharma (Pvt) Ltd., Mirpur, AJK

	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	The firm has demanded the following pack sizes: 100gm, 250gm, 500gm, 1Kg, 2.5Kg, and 5Kg	
	Decision	
	Approved	
	upto 1Kg pack size.	
703	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(XNJ-5XQ-DRVD, 2026-04-15)
	Detail of Fee Submitted	38700, 2026-04-14,
	The proposed proprietary name / brand name	FENICOLI F.R.
	Label Claim	Each 100ml contains: Florfenicol.....25gm Colistin Sulphate.....50 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 litre HDPE Bottle-De-Controlled
	Shelf Life (Unit)	2 Year(s)Belo 30 degree
	For generic drugs (me-too Status)	122550 POUL COL-25 ORAL SOLUTION of M/S. POULVET PHARMACEUTICALS (PVT) LTD, MULTAN.
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	The firm has demanded following pack sizes: 100ml, 120ml, 250ml, 500ml, 1L, 2.5L and 5L	
	Decision	
	Approved	
	upto 1L pack size.	
704	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	Acumen Healthcare (Pvt.) Ltd plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad (000932)
	Application Form Dy. No / Tracking ID & date of submission	(1G1-8WD-DRYD, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-12-19,
	The proposed proprietary name / brand name	Aglop 100mg/5ml Dry Suspension
	Label Claim	Each 5ml of reconstituted suspension contains: Cefixime as Trihydrate.....100mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temprature
	For generic drugs (me-too Status)	Trispan 100mg/5ml Dry powder for suspension (M/s Seraph Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Third generation cephalosporins
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Citi Pharma Ltd. (3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.)
	Detail of stability batches of drug product	Three batches of 300 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	N/A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted PE and CDP data against Cefspan100mg/5ml dry suspension
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	(FDA Approved) Suprax® (cefixime) for Oral Suspension USP, 100 mg/5 mL (Lupin Pharmaceuticals Inc. Baltimore, Maryland 21202 United States.)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Section approval letter attached at 1.3.5
	Evaluation Remarks	
	Decision of 354th meeting of Registration Board	Firm's response
	Deferred for confirmation of availability of 21CFR complaint HPLC system.	It is to submit with all the due reverence that our product (Aglop 100mg/5ml DS) was deferred in 354th meeting of DRB for “confirmation of availability of 21CFR complaint HPLC system.” It is to be requested that during the final compiling and composing of the CTD file of these products, due to a typographic mistake our HPLC system (used for the stability studies of these products) was declared as 21CFR non-compliant but in reality, our HPLC systems are 21CFR compliant (supporting documents attached & it was also verified physically by the inspection panel during PSI Inspection of our product Acuzith 200mg Suspension (Reg No. 133930) approved in 352nd meeting of DRB meeting). You are requested kindly to ignore and rectify this typographic mistake and consider our said applications with the status of 21CFR compliant HPLC system.
	Decision	
	Approved	
705	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	Acumen Healthcare (Pvt.) Ltd plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad (000932)

	Application Form Dy. No / Tracking ID & date of submission	(L9X-7TG-A7YH, 2026-01-02)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	ACUZITH 500MG TABLET
	Label Claim	Each film coated tablet contains: Azithromycin as Dihydrate.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	6's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temprature
	For generic drugs (me-too Status)	Zetro 500mg Tablet, M/s Getz Pharmaceuticals, Reg No. 053120
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s CITI PHARMA LTD.
	Detail of stability batches of drug product	3 batches (1000 tablets each)
	Documents for the procurement of API with approval from DRAP (in case of Import)	N/A, local purchase from Ms Citi Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP against Zyto 500mg tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	USFDA Approved (ZITHROMAX® Tablet, M/s Pfizer Labs, Division of Pfizer Inc, NY 10017, USA)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Section approval letter submitted
	Evaluation Remarks	
	Decision of 354th meeting of the Registration Board	Firm's response
	Deferred for confirmation of availability of 21CFR complaint HPLC system	It is to be requested that during the final compiling and composing of the CTD file of these products, due to a typographic mistake our HPLC system (used for the stability studies of these products) was declared as 21CFR non-compliant but in reality, our HPLC systems are 21CFR compliant (supporting documents attached & it was also verified physically by the inspection panel during PSI Inspection of our product Acuzith 200mg Suspension (Reg No. 133930) approved in 352nd meeting of DRB meeting). You are requested kindly to ignore and rectify this typographic mistake and consider our said applications with the status of 21CFR compliant HPLC system.
	Decision	
	Approved	
706	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	Acumen Healthcare (Pvt.) Ltd plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad

	(000932)
Application Form Dy. No / Tracking ID & date of submission	(PGV-M8H-3L3M, 2026-02-12)
Detail of Fee Submitted	38700, 2025-12-19,
The proposed proprietary name / brand name	Aglop 400mg Capsules
Label Claim	Each capsule contains: Cefixime as Trihydrate.....400mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	5's-As per SRO
Shelf Life (Unit)	2 Year(s)Room Temprature
For generic drugs (me-too Status)	Trispan 400mg Capsule (M/s Seraph Pharmaceuticals)
Pharmacotherapeutic Group of (API)	Third generation cephalosporins
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	M/s. Citi Pharma Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.
Detail of stability batches of drug product	3 batches, 1000 capsules each
Documents for the procurement of API with approval from DRAP (in case of Import)	N/A
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP against Cefspan 400mg capsules
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	as per zone IV conditions
The status in reference regulatory authorities	(FDA Approved) Cefixime Capsule 400mg (ALKEM LABS LTD United States.)
GMP status of the firm	New License
Evidence of approval of manufacturing facility	Section approval letter submitted
Evaluation Remarks	
Decision of 354th meeting of the Registration Board	Firm's response
Deferred for confirmation of availability of 21CFR complaint HPLC system	It is to be requested that during the final compiling and composing of the CTD file of these products, due to a typographic mistake our HPLC system (used for the stability studies of these products) was declared as 21CFR non-compliant but in reality, our HPLC systems are 21CFR compliant (supporting documents attached & it was also verified physically by the inspection panel during PSI Inspection of our product Acuzith 200mg Suspension (Reg No. 133930) approved in 352nd meeting of DRB meeting). You are requested kindly to ignore and rectify this typographic mistake and consider our said applications with the status of 21CFR compliant HPLC system.

	Decision	
	Approved	
707	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	Acumen Healthcare (Pvt.) Ltd plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad (000932)
	Application Form Dy. No / Tracking ID & date of submission	(PPM-65V-PQXZ, 2026-02-12)
	Detail of Fee Submitted	38700, 2025-12-19,
	The proposed proprietary name / brand name	Aglop 200mg/5ml Dry Suspension
	Label Claim	Each 5ml of reconstituted suspension contains: Cefixime as Trihydrate.....200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temprature
	For generic drugs (me-too Status)	Trispan 200mg/5ml Dry powder for suspension (M/s Seraph Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Third generation cephalosporins
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Citi Pharma Ltd. (3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan)
	Detail of stability batches of drug product	Three batches of 300 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	N/A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP against Cefspan 200mg/5ml dry suspension
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV conditions
	The status in reference regulatory authorities	FDA Approved (Suprax® (cefixime) for Oral Suspension USP, 200 mg/5 mL) Lupin Pharmaceuticals Inc. Baltimore, Maryland 21202 United States.
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Section approval letter attached at 1.3.5
	Evaluation Remarks	
	Decision of 354th meeting of the Registration Board	Firm's response
	Deferred for confirmation of availability of 21CFR complaint HPLC system	It is to be requested that during the final compiling and composing of the CTD file of these products, due to a typographic mistake our

HPLC system (used for the stability studies of these products) was declared as 21CFR non-compliant but in reality, our HPLC systems are 21CFR compliant (supporting documents attached & it was also verified physically by the inspection panel during PSI Inspection of our product Acuzith 200mg Suspension (Reg No. 133930) approved in 352nd meeting of DRB meeting). You are requested kindly to ignore and rectify this typographic mistake and consider our said applications with the status of 21CFR compliant HPLC system.

Decision

Approved

708	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	Acumen Healthcare (Pvt.) Ltd plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad (000932)
	Application Form Dy. No / Tracking ID & date of submission	(QWD-9XT-T5ZP, 2026-01-02)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	ACUZITH 250MG TABLET
	Label Claim	Each film coated tablet contains: Azithromycin as Dihydrate.....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	6's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temprature
	For generic drugs (me-too Status)	Zetro 250mg Tablet (M/s Getz Pharmaceuticals Registration No: 066913)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s CITI PHARMA LTD
	Detail of stability batches of drug product	3 batches of 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	N/A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP against Zyto 250mg tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	as per zone IV-A conditions
	The status in reference regulatory authorities	USFDA Approved (ZITHROMAX® Tablet, M/s Pfizer Labs, Division of Pfizer Inc, NY 10017, USA)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Section approval letter submitted
	Evaluation Remarks	
	Decision of 354th meeting of the Registration Board	Firm's response

Deferred for confirmation of availability of 21CFR complaint HPLC system	It is to be requested that during the final compiling and composing of the CTD file of these products, due to a typographic mistake our HPLC system (used for the stability studies of these products) was declared as 21CFR non-compliant but in reality, our HPLC systems are 21CFR compliant (supporting documents attached & it was also verified physically by the inspection panel during PSI Inspection of our product Acuzith 200mg Suspension (Reg No. 133930) approved in 352nd meeting of DRB meeting). You are requested kindly to ignore and rectify this typographic mistake and consider our said applications with the status of 21CFR compliant HPLC system.
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Decision

Approved

709	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	VENUS PHARMA 23-KM MULTAN ROAD, LAHORE (000300)
	Application Form Dy. No / Tracking ID & date of submission	(P73-VL3-W4Q2, 2024-03-18)
	Detail of Fee Submitted	30000.0, 2024-01-02,
	The proposed proprietary name / brand name	Stegma Tablet (50mg+500mg)
	Label Claim	Each Film Coated Tablet Contains: Sitagliptin (as Phosphate Monohydrate) 50mg Metformin HCl.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	Treviamet Tablets (50mg+500mg)
	Pharmacotherapeutic Group of (API)	Antidiabetics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name of Source: IPCA LABORATORIES LIMITED. , Address of Source: H-4 M.I.D.C., Waluj industrial area, Aurangabad – 431136, Maharashtra state, India.,Name of Source: ZHEJIANG YONGTAI PHARMACEUTICAL CO., LTD, Address of Source: No.1, 4th Donghai Road, Zhejiang Provincial chemical and medical raw material, base Linhai Zone, Linhai city, Zhejiang Prov
	Detail of stability batches of drug product	2 batches of 5000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted PE data against Treviamet tablets and CDP against Sitamet tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted as per zone IV-A conditions

	The status in reference regulatory authorities	Janumet Tablet by Merck Sharp & Dohme (UK) Limited
	GMP status of the firm	GMP certificate issued based upon evaluation conducted on 22-08-2023 and 14-09-2023
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Observation	Firm's response
	Initially, the firm has claimed as per innovator's specifications. The firm was asked to submit performance report of the drug product based on the revised specification, conducted at the next scheduled time point of the ongoing stability study since drug product monograph is available in BP 2025. Also submit supportive documents like raw data sheets and summary sheets, chromatograms of revised stability studies data.	Submitted. The firm shall submit fee for pre-approval revision of FPP specifications.
	Decision	
	Approved	
	with BP specifications. The firm shall submit fee for pre-approval variation of FPP specifications before issuance of registration letter.	
710	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	VENUS PHARMA 23-KM MULTAN ROAD, LAHORE (000300)
	Application Form Dy. No / Tracking ID & date of submission	(SA1-VLB-9AGM, 2024-03-18)
	Detail of Fee Submitted	30000.0, 2024-01-02,
	The proposed proprietary name / brand name	Stegma Tablet (50mg+1000mg)
	Label Claim	Each Film Coated Tablet Contains: Sitagliptin (as Phosphate Monohydrate) 50mg Metformin HCl.....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	Treviamet Tablet (50mg+1000mg)
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name IPCA LABORATORIES LIMITED. Address H-4 M.I.D.C., Waluj,Name ZHEJIANG YONGTAI PHARMACEUTICAL CO., LTD. Address No.1, 4th Donghai Road, Zhejiang Provincial chemical and medical raw material, base Linhai Zone, Linhai city, Zhejiang Province, 317016, China.
	Detail of stability batches of drug product	2 batches of 5000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	form-3, form-6 and form-7 submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted PE against Treviamet tablets and CDP against Sitamet tablets

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted as per zone IV-A conditions
	The status in reference regulatory authorities	Janumet by Merck Sharp & Dohme (UK) Limited
	GMP status of the firm	GMP certificate issued based upon evaluation conducted on 22-08-2023 and 14-09-2023.
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Observation	Firm's response
	Initially, the firm has claimed as per innovator's specifications. The firm was asked to submit performance report of the drug product based on the revised specification, conducted at the next scheduled time point of the ongoing stability study since drug product monograph is available in BP 2025. Also submit supportive documents like raw data sheets and summary sheets, chromatograms of revised stability studies data.	Submitted. The firm shall submit fee for pre-approval revision of FPP specifications.
	Decision	
	Approved	
	with BP specifications. The firm shall submit fee for pre-approval variation of FPP specifications before issuance of registration letter.	
711	Case Category	Contract Manufacturing (Najia Saleem)
	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	(M68-WQL-YHJD, 2024-08-21)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	C-Kolin 250mg 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 Year(s)Store below 25°C
	For generic drugs (me-too Status)	Coli wan Injection 250mg by Swan Pharma
	Pharmacotherapeutic Group of (API)	Psychostimulant and nootropics
	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	
	Evaluation Remarks	
	Initially, the firm has applied for contract manufacturing with data not already approved. The firm has now informed that subsequently same formulation C-Kolin 250mg/2ml Injection of the contract manufacturer was approved in 347th meeting of the Registration Board. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicant has submitted a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also	

	submitted as part of module-1 of Form 5F. The firm shall submit fee Rs. 9400/- for pre-approval variation as applicable on cases of cross-referred contract manufacturing.	
	Decision	
	Approved	
	The firm shall submit fee Rs. 9400/- for pre-approval variation as applicable on cases of cross-referred contract manufacturing, before issuance of registration letter.	
712	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(DW5-SU6-7MQL, 2024-07-02)
	Detail of Fee Submitted	30000.0, 2024-06-24,
	The proposed proprietary name / brand name	Seroblock
	Label Claim	Each 4ml ampoule contains: 8mg Ondansetron as ondansetron hydrochloride dihydrate.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5s-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Zofran
	Pharmacotherapeutic Group of (API)	5HT3 receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Life Sciences Block No. 251-252 Sachin-Magdalla Road GIDC, Sachin, Surat – 394 230 Gujarat, INDIA
	Detail of stability batches of drug product	3 batches of 2000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted form-3, form-6 and form-7
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Zofran injection 8mg/4ml
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted as per zone IV-A conditions
	The status in reference regulatory authorities	USFDA
	GMP status of the firm	Submitted GMP certificate based on evaluation conducted on 15-16 January 2024
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
713	Case Category	Routine (Najia Saleem)
	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	(ZXE-P36-T3PM, 2024-08-28)
	Detail of Fee Submitted	75000.0, 2024-08-21,
	The proposed proprietary name / brand name	Udacit

	Label Claim	Each Prolonged Release (Film-Coated) tablet contains: Upadacitinib hemihydrate, equivalent to 45 mg of Upadacitinib
	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 Year(s)Store below 30°C. Protect from heat, light and moisture
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	JAK inhibitor
	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	3 batches of 3000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted form-3, form-6 and form-7 along with packaging list
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP against Rinvoq 45mg tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted
	The status in reference regulatory authorities	Rinvoq Prolonged Release Tablet 45 mg by AbbVie Biotechnology Ltd
	GMP status of the firm	GMP certificate based on evaluation conducted on 06-06-2023
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
714	Case Category	Routine (Najia Saleem)
	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	(H8M-23M-QL22, 2024-08-29)
	Detail of Fee Submitted	75000.0, 2024-08-21,
	The proposed proprietary name / brand name	Udacit
	Label Claim	Each Prolonged Release (film-coated) tablet contains: Upadacitinib hemihydrate, equivalent to 30 mg of Upadacitinib
	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 Year(s)Store below 30°C. Protect from heat, light and moisture
	For generic drugs (me-too Status)	Unijak of Ms Kaizen Pharma
	Pharmacotherapeutic Group of (API)	JAK inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd
	Detail of stability batches of drug product	3 batches of 3000 tablets each
	Documents for the procurement of API with approval from DRAP	Submitted form-3, form-6 and form-7 along with packaging list

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Rinvoq 30mg tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	Rinvoq Prolonged Release Tablet 30 mg by AbbVie Biotechnology Ltd
	GMP status of the firm	GMP certificate based on evaluation conducted on 06-06-2023
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
715	Case Category	Routine (Najia Saleem)
	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	(2WS-6Y3-2SWA, 2024-09-23)
	Detail of Fee Submitted	75000.0, 2024-08-21,
	The proposed proprietary name / brand name	Udacit
	Label Claim	Each Prolonged Release (film-coated) tablet contains: Upadacitinib hemihydrate, equivalent to 15 mg of Upadacitinib
	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 Year(s)Store below 30°C. Protect from heat, light and moisture
	For generic drugs (me-too Status)	Unijak of Ms Kaizen Pharma
	Pharmacotherapeutic Group of (API)	JAK inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd
	Detail of stability batches of drug product	3 batches of 3000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted form-3, form-6 and form-7 along with packaging list
	Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted against Rinvoq tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	AbbVie Biotechnology Ltd
	GMP status of the firm	GMP certificate based on evaluation conducted on 06-06-2023
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	

716	Case Category	Routine (Najia Saleem)
	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	(TJP-PJ6-A2A9, 2024-10-09)
	Detail of Fee Submitted	93000.0, 2024-09-24,
	The proposed proprietary name / brand name	Updact
	Label Claim	Each Prolonged Release (Film-coated) tablet contains: Upadacitinib hemihydrate, equivalent to 45 mg of Upadacitinib
	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 Year(s)Store below 30°C. Protect from heat, light and moisture
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	JAK inhibitor
	Name, address of Manufacturing site:	Genix Pharma (Pvt) Ltd-Plot No. 44-45-B, Korangi Creek Road, Karachi -
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd
	Detail of stability batches of drug product	stability data of 3 batches as per zone IV-A
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted form-3, form-6 and form-7
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Rinvoq tablets 45mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	RINVOQ 45 mg (Upadacitinib Hemihydrate) Prolonged Release Tablet by AbbVie Biotechnology Ltd
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
717	Case Category	Routine (Najia Saleem)
	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	(58Z-E4R-B7WQ, 2024-10-09)
	Detail of Fee Submitted	93000.0, 2024-09-24,
	The proposed proprietary name / brand name	Updact
	Label Claim	Each Prolonged Release (Film-coated) tablet contains: Upadacitinib hemihydrate, equivalent to 15 mg of Upadacitinib

	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 Year(s)Store below 30°C. Protect from heat, light and moisture
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	JAK inhibitor
	Name, address of Manufacturing site:	Genix Pharma (Pvt) Ltd-Plot No. 44-45-B, Korangi Creek Road, Karachi -
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd
	Detail of stability batches of drug product	3 batches of 3000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted form-3, form-6 and form-7 along with packaging list
	Pharmaceutical Equivalence and Comparative Dissolution Profile	against Rinvoq 15mg tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted as per zone IV conditions
	The status in reference regulatory authorities	RINVOQ 15 mg (Upadacitinib Hemihydrate) Prolonged Release Tablet by AbbVie Biotechnology Ltd
	GMP status of the firm	submitted
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
718	Case Category	Contract Manufacturing (Najia Saleem)
	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	(L9V-EAZ-8J12, 2024-10-09)
	Detail of Fee Submitted	93000.0, 2024-09-24,
	The proposed proprietary name / brand name	Updact
	Label Claim	Each Prolonged Release (Film-coated) tablet contains: Upadacitinib hemihydrate, equivalent to 30 mg of Upadacitinib
	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 Year(s)Store below 30°C. Protect from heat, light and moisture
	For generic drugs (me-too Status)	Unijak of Ms Kaizen Pharma
	Pharmacotherapeutic Group of (API)	JAK inhibitor
	Name, address of Manufacturing site:	Genix Pharma (Pvt) Ltd-Plot No. 44-45-B, Korangi Creek Road, Karachi -
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd
	Detail of stability batches of drug product	3 batches of 3000 tablets each
	Documents for the procurement of API with approval from DRAP	Submitted form-3, form-6 and form-7 along with packaging list

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	against Rinvoq 30mg tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	as per zone IV-A conditions
	The status in reference regulatory authorities	RINVOQ 30 mg (Upadacitinib Hemihydrate) Prolonged Release Tablet by AbbVie Biotechnology Ltd
	GMP status of the firm	submitted
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
719	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate, Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(YWX-EZT-DBZZ, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-07-04,
	The proposed proprietary name / brand name	AMINOVIT ORAL SOLUTION
	Label Claim	Each Liter contains:- Vitamin A.....4000000 iu Vitamin D3.....800000 iu Vitamin E.....1600mg Vitamin B1.....2000mg Vitamin B2.....1000mg Vitamin B6.....1000mg Vitamin B12.....1000mcg Vitamin C.....1000mg Vitamin K3.....1000mg Calcium Pantothenate.....5000mg Nicotinamide.....5000mg Folic acid.....100mg Dl- methionine.....10000mg Choline Chloride.....50000mg Lysine HCl.....1000mg Biotin.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Liter -De-Controlled, 100ml, -De-Controlled, 5 Liter-De-Controlled, 500ml, -De-Controlled, 50ml, -De-Controlled
	Shelf Life (Unit)	2 Year(s) Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	ENERGIZER ORAL SOLUTION REG. NO. 063814 M/S BIOGEN PHARMA, RAWAT ISLAMABAD
	Pharmacotherapeutic Group of (API)	Multivitamins/Amino Acids/Minerals
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	

720	Evaluation Remarks	
	Decision	
	Approved	
	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(X3A-EHU-8YD5, 2025-02-23)
	Detail of Fee Submitted	37000.0, 9400 2025-02-19, 2026-03-04
	The proposed proprietary name / brand name	ETER VIRGINIA ORAL POWDER
	Label Claim	Each gram contains:- Vitamin E 9mg Vitamin D3 2mg L-Lysine 25mg DL-methionine..... 50mg Choline Chloride 50mg Virginiamycin 12mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	25Kg-De-Controlled,100gm-De-Controlled,10Kg -De-Controlled,1Kg-De-Controlled,250gm-De- Controlled,500gm-De-Controlled,5Kg-De- Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
721	For generic drugs (me-too Status)	Virgocine Oral Powder. Reg. 117048 M/S ACME Pharmaceuticals (Pvt.) Ltd.Rawat Islamabad.
	Pharmacotherapeutic Group of (API)	antibiotic+ multivitamin
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	NOBLE PHARMA B-1 OLD INDUSTRIAL AREA (000652)
	Application Form Dy. No / Tracking ID & date of submission	(84P-2Z3-85DQ, 2025-06-28)
	Detail of Fee Submitted	37000.0, 2025-06-24,
	The proposed proprietary name / brand name	NOBILEVA 3% LIQUID
	Label Claim	Each 100gm contain Levamisole HCL 3gm
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ML, 200ML, 500ML, 1L, 2.5L-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEM

	For generic drugs (me-too Status)	Levarold 3% Liquid Harold Pharma Regn. No.109078
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	overall good
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
722	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	NOBLE PHARMA B-1 OLD INDUSTRIAL AREA (000652)
	Application Form Dy. No / Tracking ID & date of submission	(P62-77U-7UBX, 2025-07-14)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	NOBILEVA-T DRANCH
	Label Claim	EACH 1000ML CONTAINS:- LEVAMISOLE.....0.015GM TRICLABENDAZOLE.....0.05GM
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ML,200ML,500ML,1L,25L-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEM
	For generic drugs (me-too Status)	LEVATRISOL-65 DRANCH Reg# 106638
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	overall good
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
723	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	NOBLE PHARMA B-1 OLD INDUSTRIAL AREA (000652)
	Application Form Dy. No / Tracking ID & date of submission	(RMZ-QWU-H31S, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-07-15,
	The proposed proprietary name / brand name	NOBIALBA 5% SUSPENSION
	Label Claim	EACH 100ML CONTAIN Albendazole 5g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ML,200ML,500ML,1L,2.5L-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	ALBANIL SUSPENSION Reg#035199

	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	OVERALL GOOD
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
724	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Izfaar Pharmaceuticals Pvt Ltd 542 A&B Sundar Industrial Estate (000800)
	Application Form Dy. No / Tracking ID & date of submission	(S9E-2E8-DY2X, 2025-01-13)
	Detail of Fee Submitted	37000.0, 2024-11-08,
	The proposed proprietary name / brand name	Cyanofar100ml Injection
	Label Claim	Cyanofar 100ml Injection Each 100ml contains: Cyanocobalamin 12.50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30
	For generic drugs (me-too Status)	cynosel by selmore phrama
	Pharmacotherapeutic Group of (API)	Vitamin B12
	Name, address of Manufacturing site:	--
	GMP status of the firm	ok
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
725	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	PRIX PHARMACEUTICA (PRIVATE) LIMITED PLOT NO.5 PHARMACITY, 30-KM MULTAN ROAD, LAHORE (000587)
	Application Form Dy. No / Tracking ID & date of submission	(SWN-14L-J2ZM, 2025-07-28)
	Detail of Fee Submitted	37000.0, 2025-07-18,
	The proposed proprietary name / brand name	BROLAX ORAL LIQUID
	Label Claim	Each 1000 ml contains; BROMHEXINE HYDROCHLORIDE =50 g
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	100 ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 15C ---30C
	For generic drugs (me-too Status)	BROM-Z Oral Liquid Reg No. 090662 Broxine-5 Oral Liquid Registration No: 117032

	Pharmacotherapeutic Group of (API)	Expectorant
	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	
	The firm has valid GMP certificate but renewal of DML inspection is pending.	
	Decision	
	Approved	
726	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(RY2-TH3-7NMG, 2025-07-07)
	Detail of Fee Submitted	37000.0, 2025-07-03, 0000-00-00
	The proposed proprietary name / brand name	ETER COLIPHATE 0.2 INJECTION(100ml)
	Label Claim	Each ml injection contains: Colistin sulphate(BP) eq.to Colistin 0.2miu
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	PRI-COLIS 0.2 INJECTION REG. NO. 080748 M/S. PRIX PHARMACEUTICALS (PVT) LTD.,LAHORE
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
727	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(MVR-97E-NYDD, 2025-07-08)
	Detail of Fee Submitted	37000.0, 2025-07-04, 0000-00-00
	The proposed proprietary name / brand name	ETER COLIPHATE 1000 INJECTION (100ML)
	Label Claim	Each ml contains:- Colistin Sulphate 1,000,000 IU (BP specifications)

	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	COLIVETO-1000 INJECTABLE SOLUTION REG. NO. 023472 M/S. VMD PAKISTAN RAWALPINDI
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
728	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(NVQ-UAM-JRL3, 2025-05-02)
	Detail of Fee Submitted	37000.0, 2025-04-23, 0000-00-00
	The proposed proprietary name / brand name	Eter Choli-Min Feed Premix
	Label Claim	Each Kg Contains:- Choline Chloride 450gm DL-Methionine 40gm L- Lysin Monohydrate 40gm Manganese Sulphate.....90gm Zinc Sulphate 22gm Vitamin B2-80 3gm Vitamin D3 5gm Di-cal-Phosphate q.s.....1kg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10Kg -De-Controlled,1Kg-De-Controlled,25Kg.- De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	Cholipol Super Feed Additive Reg. No. 023446 (M/S Symans Pharmaceuticals (Pvt.) Ltd. Lahore.)
	Pharmacotherapeutic Group of (API)	Feed Premix
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
729	Case Category	Routine (Sabahat Zehra)

	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(EPW-1J3-JP2G, 2025-07-08)
	Detail of Fee Submitted	37000.0, 2025-07-04, 0000-00-00
	The proposed proprietary name / brand name	ETER COLIPHATE 50 INJECTION(100ML)
	Label Claim	Each 100ml injection: Colistin Sulphate 50miu
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	COLISYM 50 INJECTION REG. NO. 062109 M/S. SYMANS (PVT) LTD.,SHEIKHUPURA
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
730	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(8ZZ-WYS-HLSN, 2024-12-02)
	Detail of Fee Submitted	37000.0, 9000 2024-11-26, 2025-07-09
	The proposed proprietary name / brand name	Y-GENT 11 INJECTION (100ML)
	Label Claim	Each ml contains: Gentamycin Sulphate 110mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	GENT ROLD 11 INJECTION (HAAROLDS PHARMACEUTICALS (PVT.)LTD BHIMBER AJ &K)REG. # 108986
	Pharmacotherapeutic Group of (API)	Aminoglycoside antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

731	Case Category	Import (Sabahat Zehra)
	Name, address of Applicant.	Mian Traders Railways Road, Morre Eminabad (09-341-0135-118497D)
	Application Form Dy. No / Tracking ID & date of submission	(BZU-358-ERAB, 2025-09-06)
	Detail of Fee Submitted	313500.0, 2025-08-26,
	The proposed proprietary name / brand name	AMOXOL 500
	Label Claim	EACH 100 g contains Amoxicillin trihydrate 50 g Excipients qs 100 g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1kg x 12 JAR / CARTON-De-Controlled
	Shelf Life (Unit)	2 Year(s) Store in a dry place under room temperature between 15 – 25 °C
	For generic drugs (me-too Status)	Amoxicillin Trihydrate 50g soluble powder for veterinary use is registered for use in Pakistan by companies like Bio Labs with products such as BIO-AMOXILLIN 50, and is a common antibiotic used in po
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	APA United Nano Technology Co., Ltd-Address: Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Viet Nam. Phone: +84 2839 973 778 Email: support@apanano.com Website:-Vietnam
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
732	Evaluation Remarks	
	Decision	
	Approved	
732	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(5DU-JSP-LVUM, 2025-04-16)
	Detail of Fee Submitted	37000.0, 2025-01-03,
	The proposed proprietary name / brand name	RESIDOL DUO TABLET
	Label Claim	Each film coated tablet contains: Paracetamol.....500mg Ibuprofen 200mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	2 Year(s) Store between 15°C to 30°C..
	For generic drugs (me-too Status)	PROVAS DUO TABLET (Reg.no 108579) Sami Pharmaceutical Pvt ,Ltd
	Pharmacotherapeutic Group of (API)	ANALGESIC, NSAID

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	HLT 007, HLT 008, HLT009
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provas Duo Tablet 500mg+200mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	PGP 16-006, PGP 16-005, PGP21- 001
	The status in reference regulatory authorities	Nuromol Dual Action Pain Relief 200mg/500mg tablets RECKITT BENCKISER HEALTHCARE (UK) LTD
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	Decision	
	Approved	
733	Case Category	Routine (Sabahat Zehra)
	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	(RTD-ZYA-P22J, 2024-10-10)
	Detail of Fee Submitted	37000.0, 2024-09-23,
	The proposed proprietary name / brand name	Genfix
	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 20° and 25°C
	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:	Self Manufacturing
	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) TARO PHARMACEUTICALS U.S.A,Inc.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	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	Attached
	Evaluation Remarks	
	Decision	
	Approved	
734	Case Category	Routine (Sabahat Zehra)
	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	(WHG-HU8-W9YR, 2024-10-10)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-30, 2024-09-25
	The proposed proprietary name / brand name	Peptid 20mg Tablets
	Label Claim	Each tablet contains: Famotidine.....20mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Famot 20mg Tablet, Manufacturer: Shaigan Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Histamine H2 receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	24CT121, 24CT122 , 24CT123
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: E-5739640627186
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Famot 20 Tablets by Shaigan Pharma (Pvt.) Ltd batch# 167
	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	Brand Name: Famotidine 20mg Tablet, Company: MYLAN PHARMS INC. (USFDA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
735	Case Category	Routine (Sabahat Zehra)
	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	(SN8-GQD-53VS, 2024-10-10)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-30, 2024-09-25
	The proposed proprietary name / brand name	Peptid 40mg Tablets
	Label Claim	Each tablet contains: Famotidine.....40mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Famot 40mg Tablet, Manufacturer: Shaigan Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Histamine H2 receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	24CT118, 24CT119 , 24CT120
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: E-5739640627186
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Famot 40 Tablets by Shaigan Pharma (Pvt.) Ltd batch# 124
	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	Famotidine 40mg Tablet, Company: MYLAN PHARMS INC. (USFDA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
736	Case Category	Routine (Sabahat Zehra)
	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	(VNE-SMS-9B6J, 2024-10-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-10-08
	The proposed proprietary name / brand name	Remlox 15mg Tablets
	Label Claim	Each tablet contains; Meloxicam.....15mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Xobix 15mg Tablets, Manufacturer: HiltonPharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	NSAIDS
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	YUVRAJ CHEMICALS PVT. LTD. Address: (711204), J -311,MIDC.BHOSARI,PUNE 411 026,PUNE- 411026,TALUKA BHOSARI DISTRICT,PUNE-ZONE5(India)
	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	Mobic 15mg Tablet, Company: Boehringer Ingelheim Ltd. (NDA): 020938 (USFDA Approved)
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	Decision	
	Approved	
737	Case Category	Routine (Sabahat Zehra)
	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	(EG7-SET-81U7, 2024-10-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-10-08
	The proposed proprietary name / brand name	Remlox 7.5mg Tablets
	Label Claim	Each tablet contains; Meloxicam.....7.5mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Xobix 7.5mg Tablets Manufacturer: HiltonPharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	NSAIDS
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	YUVRAJ CHEMICALS PVT. LTD. Address: (711204), J -311,MIDC.BHOSARI,PUNE 411 026,PUNE- 411026,TALUKA BHOSARI DISTRICT,PUNE-ZONE5(India)
	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	Mobic 7.5mg Tablet, Company: Boehringer Ingelheim Ltd. (NDA): 020938 (USFDA

		Approved)
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
738	Case Category	Routine (Sabahat Zehra)
	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	(BB6-R1M-JTJX, 2024-10-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-10-08
	The proposed proprietary name / brand name	Axiflox Tablets 400mg
	Label Claim	Each film coated tablet contains: Moxifloxacin (HCl) Equivalent to Moxifloxacin base 400mg (Innovator specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	MOKSI Tablet 400mg, Manufacturer: Abbott Laboratories (Pakistan) Limited.
	Pharmacotherapeutic Group of (API)	Quinolone antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	24ET97, 24ET98 , 24ET99
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: E-6402144847982
	Pharmaceutical Equivalence and Comparative Dissolution Profile	MOKSI 400mgTablets of Abbott Labs24ET97 Batch#(10): 612830XV
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	PMX-VII0409001, PMX-VII0409002, PMX-VII0409003
	The status in reference regulatory authorities	AVELOX Tablet 400mg, Company: BAYER PHARMS., (NDA): 021334, USFDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
739	Case Category	Routine (Sabahat Zehra)
	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	(P4L-16N-9LGG, 2024-10-29)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-13, 2024-09-25
	The proposed proprietary name / brand name	Emicure Tablets 10mg
	Label Claim	Each film coated tablets contains: Domperidone Maleate.....12.72mg (equivalent to 10mg Domperidone) (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Pelton-V Tablet 10mg, Manufacturer: Global Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Dopamine receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	24DT100, 24DT101, 24DT102
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-7792739642695
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pelton V 10 mg Tablets by Global Pharmaceuticals (Pvt) Ltd. Batch # 24F280
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	DM/002/08, DM/003/08, DM/004/08
	The status in reference regulatory authorities	CHEMMART DOMPERIDONE domperidone (as maleate) 10 mg Tablet, Company: Arrotex Pharmaceuticals (ARTG ID: 242334), TGA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
740	Case Category	Routine (Sabahat Zehra)
	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	(8W5-RQ6-3A71, 2024-12-19)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-11-05
	The proposed proprietary name / brand name	Numet Tablets
	Label Claim	Each tablet contains: Metronidazole.....500mg Neomycin Sulphate.....65000IU Nystatin.....100000IU (Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C

	For generic drugs (me-too Status)	Megyne Vaginal Tablets, Manufacturer: Nabiqasim Industries (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antibacterial & Antifungal agent for Vaginal Infections
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	24ET49,24ET50,24ET51
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Megyne Tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	Tergynan Tablets, ANSM France Approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Section approval letter attached
	Evaluation Remarks	
	Decision	
	Approved	
741	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Pinnacle Biotech (Pvt.) Ltd. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. (000939)
	Application Form Dy. No / Tracking ID & date of submission	(7PQ-H4R-2UA2, 2024-10-03)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-11, 2024-09-16
	The proposed proprietary name / brand name	Moxipro 400mg Tablet
	Label Claim	Each film coated tablet contains Moxifloxacin HCl equivalent to Moxifloxacin.....400mg USP Specs
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5s and 10s-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)	Avelox 400mg Tablet by Bayer Pharms
	Pharmacotherapeutic Group of (API)	Quinolone/Fluoroquinolone (antibiotic)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	ENALTEC LABS PRIVATE LIMITED
	Detail of stability batches of drug product	T-217, T-219, T-227
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: K-1948771415748
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Moxiget 400mg tablet Batch #F20003
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	EL-05/L011/1812001, EL-05/L011/1901001, EL-05/L011/1901002

	The status in reference regulatory authorities	Food and Drug Regulatory Authority USA
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
742	Case Category	Import (Sabahat Zehra)
	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	(1UE-TAP-B1HH, 2025-10-24)
	Detail of Fee Submitted	313500, 2025-08-06,
	The proposed proprietary name / brand name	Enrocure 10% Injection
	Label Claim	Enrofloxacin 10g/100 ml (Innovator's spec.) For veterinary use only
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)30 °C
	For generic drugs (me-too Status)	Reg. No. 059178 , Brand name: ENRO- PRO 10 INJECTION (10ml, 20ml, 50ml, 100ml) : Manufactured by: M/s Breeze Pharmaceuticals Pvt Ltd, Islamabad
	Pharmacotherapeutic Group of (API)	Fluroquinoloes
	Name, address of Manufacturing site:	Shandong Soocom Animal Remedy Co., Ltd-Xundakang Road No.666 of Agricultural High & New Technology Development Zone of Jinan, China-China
	Name, address of Marketing Authorization Holder:	Shandong Soocom Animal Remedy Co. Ltd., Xundakang Road No.666 of Agricultural High & New Technology Development Zone of Jinan, 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	
	Decision	
	Approved	
743	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Pinnacle Biotech (Pvt.) Ltd. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. (000939)
	Application Form Dy. No / Tracking ID & date of submission	(WQZ-SHH-RZNJ, 2024-10-29)

	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	Artepro 20mg + 120mg
	Label Claim	Each tablet contains Artemether.....20mgLumefantrine.....120mgPh Int Specs
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	16s-As per SRO
	Shelf Life (Unit)	2 Year(s)Shelf life only applies under appropriate conditions of storage specified on package.
	For generic drugs (me-too Status)	Qmetem 20mg and 120mg Tablet by Bosch Pharmaceuticals PVT LTD
	Pharmacotherapeutic Group of (API)	Antimalarial
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	VITAL LABORATORIES PVT LTD
	Detail of stability batches of drug product	T-269, T-281, T-283
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: K-1931571416289
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Qmetem 20mg/120mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Atemether; ATMS 119003, ATMS 119004, ATMS 119005 Lumefantrine: LUM 114001, LUM 114002, LUM 114003
	The status in reference regulatory authorities	COARTEM 20 mg and120 mg tablet Therapeutic Goods Administration
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
744	Case Category	Routine (Sabahat Zehra)
	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	(7BD-WBJ-4XAU, 2024-12-20)
	Detail of Fee Submitted	30000.0, 7000.0 2024-09-02, 2024-11-07
	The proposed proprietary name / brand name	BECEPTOR 5mg/5ml Oral Solution
	Label Claim	Each 5ml contains: Ebastine.....5mg Innovator's Specs.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	De-Controlled-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store over 30°C
	For generic drugs (me-too Status)	Kestine
	Pharmacotherapeutic Group of (API)	Antihistamine
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	

	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Plot No. 37/A, 38, 39, A & B, Phase-I, IDA, Jeedimetla, Hyderabad – 500 055, Telangana, India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Beceptor 1mg/ml Batch# 3U
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	Ebastel 1 mg/ml oral solution, CIMA approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Section approval letter attached
	Evaluation Remarks	
	Decision	
	Approved	
745	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Bosch Pharmaceuticals (Pvt) Ltd. Plot No. 221-223, Sector-23, Korangi Industrial Area (000350)
	Application Form Dy. No / Tracking ID & date of submission	(5GX-MJN-UNTP, 2024-11-05)
	Detail of Fee Submitted	30000.0, 7000.0 2022-09-29, 2024-11-01
	The proposed proprietary name / brand name	Supramox Drops 125mg/1.25mL
	Label Claim	Each 1.25mL reconstituted suspension contains: Amoxicillin.....125mg (as Amoxicillin Trihydrate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20mL-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C in a dry place.
	For generic drugs (me-too Status)	Oximox Drops 125mg/1.25mL
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kot Nabi Bukhwala, 34Km Ferozepur Road, Lahore.
	Detail of stability batches of drug product	TR-SUPD-02 , TR-SUPD-03, TR-SUPD-04
	Documents for the procurement of API with approval from DRAP (in case of Import)	From Pharmagen
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Amoxil Paediatric Drops 125mg/1.25mL Batch # 3T8K, Manufacturingdate: 06-2023 Manufactured by: GSK
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	000130/001/2018, 000130/002/2018, 000130/003/2018
	The status in reference regulatory authorities	Healthcare Products Regulatory Authority (HPRA)
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	

	Decision	
	Approved	
746	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(ET4-587-PDW5, 2025-07-06)
	Detail of Fee Submitted	37000.0, 9400 2025-07-04, 2026-04-17
	The proposed proprietary name / brand name	ETER NOR AG LIQUID
	Label Claim	Each 100ml contains Norfloxacin.....20gm Aminophylline.....8gm Guaiphenesin 20gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,1Liter-De-Controlled,2.5 Liter-De-Controlled,250ml-De-Controlled,500ml- De-Controlled,50ml-De-Controlled,5L-De- Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	NORAMIN-G LIQUID Reg. No . 044976 (M/S LEADS PHARMA (PVT) LTD., ISLAMABAD)
	Pharmacotherapeutic Group of (API)	Antibacterial/Bronchodilator/Expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
747	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(ZHN-MWH-S7AW, 2026-02-25)
	Detail of Fee Submitted	38700, 2026-02-25,
	The proposed proprietary name / brand name	COLISTIN F.R.
	Label Claim	Each 100 g contains: Colistin Sulphate 480 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg HDPE JAR-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 degree

	For generic drugs (me-too Status)	BIO-Colistin WaterSoluble Powder by Bio-Labs (Pvt) Ltd Islamabad
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
748	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(YBR-NBE-MRD3, 2026-02-25)
	Detail of Fee Submitted	38700, 2026-02-25,
	The proposed proprietary name / brand name	SUPERCOX F.R.
	Label Claim	Each 100g contains Sulfadimerazine Sodium 86 gm , Diaveridine HCL 10.5 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg HDPE JAR-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	Prix Pharmaceutical Pvt Ltd Lahore
	Pharmacotherapeutic Group of (API)	antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
749	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(Y4S-LU8-Q649, 2026-03-23)
	Detail of Fee Submitted	38700, 2026-03-16,
	The proposed proprietary name / brand name	CINA- F.R.

	Label Claim	Each ml contains Enrofloxacin... 75 mg, Sulphamethoxypyridazine... 50 mg, Sulphamethazine... 50 mg, Trimethoprim... 25 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 litre HDPE Bottle-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	M/S. Bio-Oxime Pharmaceuticals Faisalabad
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	The applied formulation contains 4 antibiotics, under review of sub-committee on veterinary drugs.	
	Decision	
	Deferred	
	For submission of valid international references in support of their product, if available	
750	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(WNY-V85-ZUPX, 2026-02-25)
	Detail of Fee Submitted	38700, 2026-02-20,
	The proposed proprietary name / brand name	AMPROLIUM 50 F.R.
	Label Claim	Each gram contains AMPROLIUM HCL 50 0mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg HDPE JAR-De-Controlled
	Shelf Life (Unit)	2 Year(s)Belo 30 degree
	For generic drugs (me-too Status)	Bio-Labs (Pvt) Ltd Islamabad
	Pharmacotherapeutic Group of (API)	Anticoccidial
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Target species is poultry.	
	Decision	
	Approved	
751	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(S3D-JUY-QMMB, 2026-02-21)

	Detail of Fee Submitted	38700, 2026-02-20,
	The proposed proprietary name / brand name	FNC 100 F.R.
	Label Claim	Each Kg contains: Furaltadone HCL 75 g Neomycin SulPhate 30 g Chlortetracycline HCL 100 g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg HDPE JAR-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	Trifle WSP Selmore Pharmaceutical Pvt Ltd
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Formulation contains FURLTADONE and target species is poultry.	
	Decision	
	Deferred	
	The instant case for review of formulation to Sub-committee on veterinary drugs.	
752	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(R2E-ERH-BE9N, 2026-02-21)
	Detail of Fee Submitted	38700, 2026-02-20,
	The proposed proprietary name / brand name	CTC F.R.
	Label Claim	Each kg contains Chlortetracycline hydrochloride 200 g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg HDPE JAR-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	Bio-CTC20Water Soluble Powder by Bio-Labs (Pvt) Ltd Islamabad
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
753	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL

		CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(W5H-5N8-NHW9, 2026-02-12)
	Detail of Fee Submitted	38700, 2026-02-12,
	The proposed proprietary name / brand name	T-DOX F.R.
	Label Claim	Each 100 gram contains Tylosin Tartrate 20.00 g Doxycycline Hyclate 40.00 g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg HDPE JAR-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	BIO-DOXYTIL WATER SOLUBLE POWDER Reg# 105029 by Bio-Labs (Pvt) Ltd Islamabad
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
754	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(RJB-Q37-5UND, 2026-02-27)
	Detail of Fee Submitted	38700, 2026-02-26,
	The proposed proprietary name / brand name	OXY-N F.R.
	Label Claim	Each g contains: Oxytetracycline HCl 300 mg, Neomycine Sulphate 150 mg, Florfenicol 100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg HDPE JAR-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	Baariq Pharmaceuticals lahore
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	

755	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(L5V-QR7-UXAH, 2026-03-05)
	Detail of Fee Submitted	38700, 2026-03-03,
	The proposed proprietary name / brand name	ENRO + PLUS F.R.
	Label Claim	Each 100ml contains Enrofloxacin 25 g, Colistin Sulphate 50 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 litre HDPE Bottle-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	Vetz Pharmaceutical Pvt Ltd Kotri, Sindh
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
756	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(86S-88B-X9NT, 2026-02-21)
	Detail of Fee Submitted	38700, 2026-02-20,
	The proposed proprietary name / brand name	ERYTYL F.R.
	Label Claim	Each kg contains Tylosin B.P 50 gm, Erythromycine Thiocyanate 60 gm, Fulraltadone HCL 140 GM
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg HDPE JAR-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	Erytyl-F WSP A&K Pharmaceutical sargodah road Faisalabad
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Formulation contains FURALTADONE	
	Decision	

	Deferred	
	The instant case for review of formulation to Sub-committee on veterinary drugs.	
757	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	FORZA ROMA PHARMACEUTICAL PVT LTD PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD (001020)
	Application Form Dy. No / Tracking ID & date of submission	(A2X-RX6-P23P, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-26,
	The proposed proprietary name / brand name	BROMO F.R, 5%
	Label Claim	Each 100ml contains 5g OF BROMHEXINE
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 litre HDPE Bottle-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	Bromomont OralLiquid by Westmont Pharmaeutial industry Rawalpindi
	Pharmacotherapeutic Group of (API)	Expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
758	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	QADIR PHARMACEUTICALS FATEH GHAR SAHUWALA ROAD SIALKOT (000944)
	Application Form Dy. No / Tracking ID & date of submission	(Q86-XGJ-U1AZ, 2024-07-19)
	Detail of Fee Submitted	30000.0, 2024-07-12,
	The proposed proprietary name / brand name	Ulci-Q 40mg
	Label Claim	Each film coated tablet contains Famotidine 40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x10's=20's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Me-Too
	Pharmacotherapeutic Group of (API)	Antiulcerative
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SMS Life Sciences INDIA Ltd.
	Detail of stability batches of drug product	TTR090, TTR091, TTR092
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: K-1829907556325

	Pharmaceutical Equivalence and Comparative Dissolution Profile	ACICON 40mg by Barrett Hodgson Pakistan (PVT) Ltd Batch # D5972
	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	EMC, FDA HPRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
759	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(96P-PVY-H496, 2024-10-21)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-10, 2024-10-18
	The proposed proprietary name / brand name	LINZE
	Label Claim	Each 300ml contains Linezolid USP 600mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	300mlx1's, 300mlx10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	Zoldap Infusion 600mg/300ml by Getz
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	Surge laboratories private limited-10TH KM FAISALABAD ROAD, BIKHI DISTRICT,, SHEIKUPURA, Sheikhupura Sheikhupura-
	Name & address of API manufacturer	Optimus Drugs Private Limited
	Detail of stability batches of drug product	3 Batches LZ2-001C, LZ2-002C, LZ2-003C
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xyvox IV Infusion 600mg/300ml Mfd by: Pfizer Laboratories
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 Batches OP-LIZ-S2-002/13, OP-LIZ-S2-003/13, OP-LIZ-S2-004/13
	The status in reference regulatory authorities	FDA Approved - Zyvox [Linezolid] Injection for intravenous use - Pfizer
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	Decision	
	Approved	
760	Case Category	Routine (Sabahat Zehra)

	Name, address of Applicant.	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi. (000105)
	Application Form Dy. No / Tracking ID & date of submission	(P34-MWJ-H45E, 2024-10-21)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-10, 2024-10-18
	The proposed proprietary name / brand name	LINZE
	Label Claim	Each 100ml contains Linezolid USP 200mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml x 1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	Zoldap Infusion 200mg/100ml by Getz
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	Surge laboratories private limited-10TH KM FAISALABAD ROAD, BIKHI DISTRICT,, SHEIKUPURA, Sheikhpura Sheikhpura-
	Name & address of API manufacturer	Optimus Drugs Private Limited
	Detail of stability batches of drug product	LZ1-001C, LZ1-002C, LZ1-003C
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	uct Name: Nezocin Infusion 200mg/ 100ml Mfd by: Brookes
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	OP-LIZ-S2-002/13, OP-LIZ-S2-003/13, OP-LIZ-S2-004/13
	The status in reference regulatory authorities	FDA Approved - Zyvox [Linezolid] Injection for intravenous use - Pfizer
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
761	Case Category	Contract Manufacturing (Saima Hussain)
	Name, address of Applicant.	Bosch Pharmaceuticals (Pvt) Ltd. Plot No. 221-223, Sector-23, Korangi Industrial Area (000350)
	Application Form Dy. No / Tracking ID & date of submission	(UJS-EM6-YDYU, 2024-08-21)
	Detail of Fee Submitted	75000.0, 2024-04-23,
	The proposed proprietary name / brand name	Bemprix - EZ (Bempedoic Acid + Ezetimibe) Tablets 180mg
	Label Claim	Each film coated tablet contains: Bempedoic acid 180mg Ezetimibe.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's, 1x10's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C

	For generic drugs (me-too Status)	Bempid Eze Tablets 180mg +10mg
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot # 129, Sunder Industrial Estate Lahore, Pakistan-
	Name & address of API manufacturer	Metrochem API (Pvt.) Ltd. Address: Unit-IV, Plot No. 34B, 40 B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, 531021, India (IND)., Saptagir Laboratories (Pvt.) Ltd. Address: SyNo Parts of 27, 46 & 50 to 56, Ananthasagar (Vill), Chegunta (Mandal), Medak (Dist.), Telegana, India-502 247
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	U.S. Food and Drug Administration
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Registration Board in its 348th meeting approved the product Nextol -EZ 180mg/10mg Tablet Label Claim Each Film Coated tablet contains: Bempedoic Acid.....180mg Ezetimibe.....10mg in the name of M/s. Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789). In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement 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 per the current Fee SRO prior the issuance of Registration Letter.	
762	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(YJ7-XSP-A4U2, 2024-10-28)
	Detail of Fee Submitted	37000.0, 2024-10-24,
	The proposed proprietary name / brand name	Coliferol
	Label Claim	Each mL (ampoule) contains Cholecalciferol (Vitamin D3) 200,000IU/mL * 200,000IU of Cholecalciferol (Vitamin D3) is equivalent to 5mg of Cholecalciferol (Vitamin D3)
	Reference to Finished product specifications	Manufacturer Specification

Proposed Pack Size		1's -As per SRO
Shelf Life (Unit)		24 MonthStore below 25°C
For generic drugs (me-too Status)		INDROP D (NEUTRO PHARMA)
Pharmacotherapeutic Group of (API)		
Name, address of Manufacturing site:		Self Manufacturing
Name & address of API manufacturer		SICHUAN PROVINCE YUXIN PHARMACEUTICAL CO., LTD 51, West Section of Changjiang Road, Economic Development District (South District), Shifang City, Sichuan Province, China 618400
Detail of stability batches of drug product		
Documents for the procurement of API with approval from DRAP (in case of Import)		
Pharmaceutical Equivalence and Comparative Dissolution Profile		
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		
The status in reference regulatory authorities		Vitamin D3 Good 200,000 IU/ 1 mL 1M Solution for Injection Sante.Fr (ANSM, France)
GMP status of the firm		
Evidence of approval of manufacturing facility		
Evaluation Remarks		
Sr.no.	Observations	Response of the Firm
1	Provide the reference of international guidelines/Pharmacopeial general chapter which allow the overage of up to 20% to compensate for degradation during manufacture or a product’s shelf life.	Firm in their reply submit updated formulation without BUTYLATED HYDROXYANISOLE and no overages along with all relevant supporting data, including: Pharmaceutical development Comparative studies Finished product analytical data (FP Specifications, Analytical Testing Procedure, Batch Analysis) Stability studies (3 batches 250 ampoule each)along with raw data (data loggers, audit trails) Production documentation
2	Provide the evidence of reference product approved in RRA, that has used BUTYLATED HYDROXYANISOLE as an antioxidant in their Cholecalciferol injection.	
Decision		
Approved		
Firm shall submit fee for pre- registration variation as per the latest Fee SRO prior the issuance of Registration Letter.		
Case Category		Contract Manufacturing (Saima Hussain)
Name, address of Applicant.		AUSPEC PHARMACEUTICALS PVT LTD 21, Km, Raiwind Road, Lahore. (000964)
Application Form Dy. No / Tracking ID & date of submission		(WJL-W1S-7NZQ, 2024-05-22)
Detail of Fee Submitted		75000.0, 2024-02-06,
The proposed proprietary name / brand name		Sanarte 30mg Injection
Label Claim		Each Vial contains: Artesunate. 30mg
Reference to Finished product specifications		The International Pharmacopeia

Proposed Pack Size	I's / DPC-As per SRO
Shelf Life (Unit)	2 Year(s)Store Below 25C
For generic drugs (me-too Status)	Gen-M Injection by M/s Genix Pharma
Pharmacotherapeutic Group of (API)	Antimalarial
Name, address of Manufacturing site:	Aulton Pharmaceuticals-Plot # 84/1, Block A, Phase 5, Industrial Estate, Pakistan-
Name & address of API manufacturer	MICRO ORGO CHEM, C-1/B-57, LIC Sector, GIDC Vapi-396 195, Gujarat.
Detail of stability batches of drug product	Stability data of 3 batches (5000 vials each) is submitted by the firm
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is attached.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against the Comparator product (Gen-M Injection)
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of drug substance as per zone-IV condition is submitted by the firm.
The status in reference regulatory authorities	Artesunate 30mg Injection by M/s Amivas LLC, 600 Capability Green,Luton,LU1 3LU, USA.
GMP status of the firm	GMP certificate of year 2021 is submitted
Evidence of approval of manufacturing facility	Renewal of DML letter dated 3rd November,2015 mentioned that firm has Liquid Injectable(general) section

Evaluation Remarks

Sr.no.	Observations	Response of the Firm
1.	Justify the omission of the system suitability test during the assay verification of the drug substance by the drug product manufacturer, considering that the International Pharmacopoeia method specifies that the test is not valid unless the peak-to-valley ratio (Hp/Hv) is at least 5.0.	Firm in their reply stated that, during verification, acceptable chromatographic performance was demonstrated through consistent retention time, peak shape, and repeatability. Hence, omission of the Hp/Hv system suitability test does not impact assay reliability or product quality.
2.	Justify for not using the same solvent for reconstitution of the powder for injection as recommended by the WHO prequalified finished product during the in-use stability study of the drug product. Additionally, explain why the storage conditions and duration applied in the study differ from those specified in the available literature of the WHO prequalified product.	Firm replied that, to reconstitute Artesunate powder for injection, first use the provided Sodium Bicarbonate solvent (usually 1 mL) to dissolve the powder into a clear solution, then immediately dilute that solution further with 0.9% Sodium Chloride (saline) or 5% Glucose (dextrose) for IV/IM administration, as artesunate is unstable in water and must be used within an hour. Further, the in-use stability study of Artesunate 30 mg powder for injection was performed using the solvent intended to be supplied with the applicant's product, as in-use stability is required to represent the actual marketed presentation. Use of the WHO-prequalified product solvent would not reflect the intended clinical use of the applicant's formulation. The selected solvent is pharmaceutically acceptable, compatible with artesunate. However, the reference product literature

		revealed that accompanied solvent is, each ampoule of 1.5 mL solvent contains arginine 20 mg/mL and sodium bicarbonate 8.4 mg/mL.
3.	Justify for not including the system suitability parameter during the assay performance, considering that the International Pharmacopoeia specifies that the test is not valid unless the peak-to-valley ratio (Hp/Hv) is at least 5.0. Additionally, provide a rationale for the elution of the impurity C peak during the standard run, given that the impurity C peak is consistently observed in all standard chromatograms.	Firm replied that, the $Hp/Hv \geq 5.0$ criterion specified in the International Pharmacopoeia is a method validity requirement primarily applicable during method development and validation. During verification, acceptable chromatographic performance was demonstrated through consistent retention time, peak shape, and repeatability. Hence, omission of the Hp/Hv system suitability test does not impact assay reliability or product quality. SENATE 30MG INJECTION (DEFICIENCY REPLY) Impurity C is a known process-related impurity of Artesunate API. The working standard is prepared from API manufactured by the same synthetic route and therefore contains trace levels of this impurity. The validated analytical method is capable of resolving Impurity C with adequate specificity, resulting in its consistent elution in the standard chromatogram. However, the IP monograph of Artesunate injection stated that the chromatogram obtained with solution (1 sample solution) may show a peak due to impurity C eluting at a relative retention of about 2.7 with reference to artesunate.
4.	Submit the valid GMP certificate of API manufacturer.	Firm again submitted the expire GMP certificate of API Manufacturer. (15/09/2021 to 14/09/2023.)
Decision		
Approved		
Registration Board approved the product subject to the submission of in-use stability studies of the drug product using the same solvent as recommended by the WHO prequalified reference product. The firm shall also submit batch analysis report in accordance with IP monograph of Artesunate Injection.		
764	Case Category	Contract Manufacturing (Saima Hussain)
	Name, address of Applicant.	jupiter Pharma Plot No 25 Street S-6 RCCI Rawat Rawalpindi (000838)
	Application Form Dy. No / Tracking ID & date of submission	(WPY-2R3-L4NY, 2024-06-21)
	Detail of Fee Submitted	75000.0, 2024-02-02,
	The proposed proprietary name / brand name	Dexxo 60mg Capsule
	Label Claim	Each Capsule Contains: Dexlansoprazole Dual Delayed Released Pellets eq. to

	Dexlansoprazole.....60MG (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 25°C
For generic drugs (me-too Status)	Dexxo Capsule by Weather Folds Pharma.
Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar.-
Name & address of API manufacturer	Winbrains Research Laboratories
Detail of stability batches of drug product	Stability data of three batches of batch size 1200 capsule each is submitted by the firm. (Only 6 months)
Documents for the procurement of API with approval from DRAP (in case of Import)	Pellets procured locally from M/s. Winsbrains
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have performed against the product DEXILANT 60mg capsules B. No: 532477
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV condition is submitted
The status in reference regulatory authorities	USFDA Approved
GMP status of the firm	GMP certificate for export dated 28-10-2022 is submitted
Evidence of approval of manufacturing facility	GMP certificate mentioned that firm has capsule section

Evaluation Remarks

Sr.no.	Observations	Response of the Firm
1.	Real time stability studies of Dexlansoprazole DDR pellets till 6 months is submitted, submit real time stability studies of pellets till complete shelf life.	Firm submitted the stability data of drug substance till the claimed shelf life.
2.	Clarify the discrepancy in the reported batch sizes of the stability batches. In section 3.2.P.8.1, the batch size is stated as 5,000 packs for each of the three batches, whereas in section 3.2.P.8.3, the batch size is reported as 1,200 capsules for each of three different batches.	Firm replied that, mistakenly 5000 pack written in summary sheets, Revised and correct attached. Firm submitted stability data of only six months.

Decision

Approved

Firm shall submit fee of pr-registration variation as per the latest fee SRO, prior the issuance of Registration letter.

765	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	NovaMed Pharmaceuticals(Pvt.)Ltd 28-KM Ferozepur Road Lahore (000590)
	Application Form Dy. No / Tracking ID & date of submission	(PVL-Y6A-2TBM, 2024-06-13)
	Detail of Fee Submitted	30000.0, 2024-05-21,
	The proposed proprietary name / brand name	Iben-Q
	Label Claim	Each 100ml Vial contains: Ibuprofen.....400mg
	Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	1's(100ml)-As per SRO	
Shelf Life (Unit)	2 Year(s)store below 25°C	
For generic drugs (me-too Status)	Boschofen	
Pharmacotherapeutic Group of (API)	NSAID	
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer	Hubei biocause Heilen Pharmaceutical Co., Ltd.	
Detail of stability batches of drug product	stability data of three batches RD/PR23-056-T1-S1, RD/PR23-056-T1-S2, RD/PR23-056-T1-S3 (50 vials batch size each)	
Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP attested commercial invoice attached	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE PERFORMED AGAINST THE COMPARATOR PRODUCT Boschofen Infusion 400mg/100ml B#BS240003	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of drug substance as per zone-IV condition is submitted	
The status in reference regulatory authorities	Ibuprofen 400 mg solution for infusion By MHRA	
GMP status of the firm	Firm submitted renewal of DML approval letter dated 14th September,2021.	
Evidence of approval of manufacturing facility	Firm submitted grant of additional section letter dated 29th August,2013 mentioned that firm has General Liquid Injection Vial (SVP).	
Evaluation Remarks		
Sr.no.	Observations	Response of the Firm
1.	Rationalize the selected trial batch size with respect to the total number of vials required to perform all quality control tests, including those necessary to support stability studies up to the proposed shelf life.	Firm replied that the development stage selected trial batch size of 50 vials was determined based on testing consumption requirements in accordance with ICH Q1A and DRAP expectations. The batch size adequately supports release testing, stability studies at long-term and accelerated conditions across all time points, and retention samples. Approximately 40-45 vials.
2.	The target fill volume of the applied infusion is 100 mL,then justify the adjustment of the quantities of the API and all excipients based on a volume of 102 mL.	Firm replied that the target fill volume of the finished pharmaceutical product is 100 mL, During trial manufacturing, the formulation was prepared with a slight overage (102 mL) to compensate for unavoidable processing losses at lab scale level such as:• solution transfer,• Filling-related volume losses.Accordingly, the quantities of API and excipients were calculated based on 102 mL bulk volume to ensure that each final container delivers the label claim concentration per 100 mL. This approach is to ensures compliance with assay, content

		uniformity, and finished product specifications. It is clarified that the target filled, labeled, and released volume is 100 mL.
Decision		
Approved		
766	Case Category	Import (Saima Hussain)
	Name, address of Applicant.	AM Pharma Pvt Ltd 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan. (262)
	Application Form Dy. No / Tracking ID & date of submission	(NVH-2ZM-S2H8, 2025-05-30)
	Detail of Fee Submitted	75000.0, 225000.0 2024-12-31, 2025-05-20
	The proposed proprietary name / brand name	Gadobutrol Injection
	Label Claim	Each 7.5ml vial contain: Gadobutrol 4.5354gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO, 10's-As per SRO
	Shelf Life (Unit)	36 Year(s) Store at 25°C
	For generic drugs (me-too Status)	Gadovist, Registration Number: 072541
	Pharmacotherapeutic Group of (API)	Gadolinium-based contrast agent
	Name, address of Manufacturing site:	Jiangsu Hengrui Pharmaceuticals Co., Ltd.-38 Huanghe Road, Economic & Technological Development Zone, Lianyungang, Jiangsu, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparison studies performed against Reference Listed Drug GADAVIST® (Gadobutrol) Injection by BAYER HEALTHCARE PHARMACEUTICALS .INC
	Name, address of Marketing Authorization Holder:	AJM Pharma (Pvt) Ltd., 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Firm submitted Drug Manufacturing Certificate dated 13th may, 2024 issuance agency: Jiangsu Medical Products Administration
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data is submitted
	The status in reference regulatory authorities	Gadavist (Gadobutrol) Injection, Manufacturer Name: Bayer HealthCare Pharmaceuticals Inc. Brand Name: Gadavist® Strength: 1.20944 g/2 mL, 4.5354 g/7.5 mL, 6.0472 g/10 mL, 9.0708 g/15 mL Dosage Form: Injection Pack Size: cartons of 10, Boxes of 20 Registration Number: NDA 201277
	Evaluation Remarks	
	Submit valid and legalized CoPP issued by the regulatory authority of country of origin, since the submitted CoPP has not been verified from the official website of NMPA, China. Firm replied that, we hereby confirm that the previously submitted Appostile COPP (Certificate No. Jiangsu20240490)	

is authentic and verifiable on the official website of the National Medical Products Administration (NMPA). However, the CoPP available on the NMPA website is invalid.

Decision

Approved

Subject to compliance of current Import Policy for finished drugs along with submission of valid and original legalized COPP before issuance of registration letter

767	Case Category	Import (Saima Hussain)
	Name, address of Applicant.	Bristol Mayer Biotech Pakistan 73 B Guldasht Town Zarrar Shaheed Lahore (05-352-0068-109282D)
	Application Form Dy. No / Tracking ID & date of submission	(MLH-Q77-6TS2, 2025-04-09)
	Detail of Fee Submitted	300000.0, 2025-03-10,
	The proposed proprietary name / brand name	Dydrogesterone 10mg BP
	Label Claim	Each film coated tablet contains: Dydrogesterone BP.....10 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	36 Year(s)Store in a cool and dry place. Protect from direct light.
	For generic drugs (me-too Status)	Duphaston 10mg Tablets by Abbott Laboratories (Pakistan) Limited
	Pharmacotherapeutic Group of (API)	Synthetic Progesterone
	Name, address of Manufacturing site:	ACCENT PHARMACEUTICALS & DIAGNOSTICS-Vill. Bhalon (Seri), Forest Road, Solan-173212 Himachal Pradesh, India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative studies have been submitted.
	Name, address of Marketing Authorization Holder:	ACCENT PHARMACEUTICALS & DIAGNOSTICS, Vill. Bhalon(Seri), P.O. Galanag Forest Road, Solan-173212, Himachal Pradesh, India, India
	Details of Certificates (CoPP/FSC/cGMP):	Firm submitted GMP certificate Certificate No.DCA/SLN/DML/108/10 dated 09/05/2025 is submitted by the firm.
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data has submitted
	The status in reference regulatory authorities	HPRA (Ireland Approved) Duphaston 10 mg film coated tablets by Theramex Ireland Limited

Evaluation Remarks

Sr.no.	Observations	Response of the firm
1.	Submit a valid, original, and duly legalized Certificate of Pharmaceutical Product (CoPP) or Free Sale Certificate issued by the relevant regulatory authority of the country of origin.	Firm submitted the CoPP certificate no. DCA/SLN/DML/108/10(Vol-II)/25/105 dated 13-Nov.-2025 issued by Assistant Drugs Controller Cum Licensing Auth Baddi, Distt Solan (HP)

2.	Submit a valid and duly legalized Letter of Authorization for the applied product.	Letter of Authorization dated 01/12/2025 is submitted by the firm.
3.	Provide a valid Good Manufacturing Practice (GMP) certificate for the manufacturer abroad, issued by the competent regulatory authority.	Firm submitted GMP certificate Certificate No.DCA/SLN/DML/108/10 dated 09/05/2025 is submitted by the firm.
4.	Provide a scientific justification for the formulation composition of the applied product, which contains multiple excipients, including five disintegrants and four diluents, and involves the use of dichloromethane (a Class 2 solvent) as a binder during wet granulation. Justify its use considering its inherent toxicity and regulatory limitations. Additionally, provide evidence or literature/reference supporting that the reference (innovator) product recommends or employs a similar formulation approach.	Firm replied that the formulation of Dydrogesterone Tablets BP uses multiple excipients selected based on compatibility studies, prior pharmaceutical knowledge, and optimization trials to achieve desired tablet properties like flow, disintegration, and stability. Dichloromethane, a Class 2 solvent per ICH Q3C guidelines, is employed as a granulation solvent to dissolve Povidone K30 binder effectively, ensuring uniform granules despite the drug's poor aqueous solubility, with complete removal validated by achieving low LOD (1.5-2.0%) during drying. However, the residual solvent test is included in the drug product specification.
5.	Clarify the submission of an analytical method validation protocol for spironolactone tablets instead of dydrogesterone tablets. Furthermore, justify the low absorbance (approximately 0.22) observed during assay validation studies, and discuss its suitability for accurate quantification, considering potential instrumental noise at lower absorbance levels. Also, specify the minimum acceptable absorbance for reliable measurement. Submit the calibration curve used for dissolution testing, along with the UV spectrum of the applied product.	Firm has not submitted the reply of this query.

Decision

Rejected

The Registration Board has decided to reject the present application based on the following deficiencies:

The firm has failed to provide adequate scientific justification, along with supporting evidence of a reference product, for the inclusion of four different types of disintegrants and four different types of diluents in the proposed formulation. The rationale for using multiple excipients with potentially overlapping functionalities has not been established, nor has any evidence been submitted to demonstrate that such a composition is aligned with an approved or reference-listed product.

Furthermore, the firm has not provided any evidence indicating that the reference product uses a Class II solvent, namely dichloromethane, in the manufacturing process of the dydrogesterone tablet. The applicant has neither justified its use nor addressed compliance with applicable regulatory guidelines. In addition, the firm has not included test for residual solvents in the finished product specifications to ensure that solvent levels, if present, remain within acceptable safety limits. In addition, the use of dichloromethane as an excipient in the manufacturing of locally produced drug products is prohibited by DRAP.

The firm has not provided any clarification or justification for the discrepancy regarding the submission of analytical method validation protocol for spironolactone tablets instead of dydrogesterone tablets.

Firm has not justified the low absorbance value (approximately 0.22) observed during assay validation studies. The suitability of such a low absorbance for accurate quantification has not been discussed, particularly in relation to potential instrumental noise and reduced analytical sensitivity at lower absorbance levels.

The firm has not submitted the calibration curve used for dissolution testing nor provided the corresponding UV absorption spectrum of the applied product.

768	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	Martin Dow Marker Limited 7, Jail Road Quetta. (000028)
	Application Form Dy. No / Tracking ID & date of submission	(D14-735-SZYD, 2024-04-30)
	Detail of Fee Submitted	75000.0, 2023-12-07,
	The proposed proprietary name / brand name	Dolo Neurobion
	Label Claim	Each Capsule contains: Diclofenac Sodium 50mg Thiamine Hydrochloride.....50mg Pyridoxine Hydrochloride.....50mg Cyanocobalamin.....0.25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10'sx3-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	NSAIDs & Multivitamins
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	DSM Nutritional Products Europe Ltd.,Ningbo Smart Pharmaceutical Co., Ltd. ,Supreem Pharmaceutical India.
	Detail of stability batches of drug product	stability data of three batches (5000 capsule) each
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP attested invoice of all three API is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has performed against the reference product Diclovit Capsules (Thiamine HCl, Pyridoxin HCl, Diclofenac sodium & Cyanocobalamin), Batch No. 1A140A manufactured by G.L Pharma GmbH, 8502 Lannach
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of all three-drug substance performed as per zone-IV condition is submitted by the firm.

The status in reference regulatory authorities	Diclovit Capsule (Austria)
GMP status of the firm	GMP Certificate dated 10th September,2021 is submitted by the firm.
Evidence of approval of manufacturing facility	GMP Certificate dated 10th September,2021 is submitted by the firm mentioned that firm has capsule (general section)

Evaluation Remarks

Sr.no.	Observations	Response of the Firm
1.	Since the polymer Acryl-EZE White 93018509 has been used in the applied formulation to achieve delayed/modified release of diclofenac sodium, justify the observed dissolution behavior showing more than 28% release in 0.1 N HCl within 60 minutes, whereas the acceptance limit for the acid stage is NMT 10% release within 2 hours. Further, clarify the rationale for not including the acid-resistance stage in the dissolution test of the finished product.	Firm replied that, although the observed dissolution behavior during the Comparative Dissolution Profile (CDP) study showed more than 28% drug release in 0.1 N HCl within 60 minutes, this behavior is consistent with that of the Innovator product under identical CDP conditions. Furthermore, the dissolution specification for Diclofenac Sodium finished product has been revised to include the following stages in line with the requirement of USP: Acid stage (0.1 N HCl) Buffer stage (pH 6.8) Dissolution testing has been conducted in accordance with the revised specification on freshly manufactured batches of DoloNeurobion capsule i.e., PDS-468/25 and PDS-469/25 by maintaining the same product formulation used for primary batches. However, previously manufactured primary batches of DoloNeurobion capsule have expired and are no longer available for any valid testing.
2.	As the individual monographs of drug product containing Thiamine HCl and Pyridoxine HCl in the USP include a dissolution test, justify for not including the dissolution test in the fixed-dose combination containing these APIs.	The finished product specification has now been revised to include dissolution testing for both Thiamine HCl and Pyridoxine in line with the individual USP monographs requirement. Accordingly performance report of freshly prepared batches has been submitted.

Decision

Approved

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

769	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, excursion 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.
Decision		

Deferred

Registration Board 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.

770	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.

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.

Decision

Deferred

Registration Board 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.

771	Case Category	Import (Saima Hussain)
	Name, address of Applicant.	Leven Medical Care 8-C STREET 3 (05-352-0063-034960D)
	Application Form Dy. No / Tracking ID & date of submission	(1EV-7A7-YTEE, 2026-02-03)
	Detail of Fee Submitted	75000.0, 225000 2025-05-14, 2025-11-04
	The proposed proprietary name / brand name	Lixafert
	Label Claim	Cetrotide (as acetate) 0.25 mg powder and solvent for solution for injection Each pack contain two sterile vials of powder for solution for injection, Each vial contain 0.25mg Cetrotide (as acetate)

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	Subject: Cover Lette-As per SRO
	Shelf Life (Unit)	2 Year(s)2C to 8C
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	Pharmaceutical API-GnRH antagonist
	Name, address of Manufacturing site:	CinnaGen Co.-Plot 72,74,87,88, 3rd Sq, Simin Dasht Non-Governmental Industrial Area, Fardis County, Alborz Province Iran-Iran
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Yes-Attached-Module 3- page no 2103
	Name, address of Marketing Authorization Holder:	LEVEN MEDICAL CARE, 8-C, Street 3, Shah Jamal Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	yes
	Details of Authorization Letter :	Yes attached-Module 3-Page no-164,165,166
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Yes-Attached-Module 3- page no.2259
	The status in reference regulatory authorities	Yes
	Evaluation Remarks	
	Please clarify whether the applied product (Cetorelix acetate is a linear decapeptide with a molecular weight of 1431, which comprises five L-amino and five D-amino acids including 1-2 mol acetic acid par 1 mol peptide(is manufactured in the same facility and on the same vial filling line used for human recombinant proteins (e.g., interferons), as indicated in Annex-2 (List of SD2 Facility Products) submitted with the Site Master File. Alternatively, confirm whether a segregated or dedicated facility is used for the manufacture of the applied synthetic pharmaceutical product (cetorelix/Lixafert). Kindly provide clarification along with supporting documentary evidence. We would like to clarify that the bulk manufacture of CHO-derived recombinant products, as well as the formulation and filling (vials and prefilled syringes), are performed within the SD2 facility. For Cetorelix (Lixafert), it should be noted that the drug substance (DS) is procured from Piramal Pharma, and no DS manufacturing activities are performed at SD2. The activities conducted at SD2 are limited to formulation and aseptic filling of the Lixafert. Within SD2, all operations are carried out in segregated areas, with dedicated rooms and classified cleanroom suites assigned to each product type and process. The handling of recombinant biologics and chemical products is performed in separate rooms and cleanroom environments, ensuring no operational or physical overlap. In SD2, appropriate facility design, HVAC systems, personnel and material flow controls, and validated cleaning procedures are implemented to maintain segregation and prevent any risk of cross-contamination, in full compliance with GMP requirements. The SD2 facility holds a valid EU GMP certificate, which is provided in which it is stated that, "This inspection covered the Manufacturing site: SiminDasht 2 (SD2) only includes manufacture of biological active substances and dosage forms containing biological active substance.	
	Decision	
	Rejected	
	The Registration Board has decided to reject the instant application on the basis that the applied pharmaceutical product is manufacture within the same facility where biological products, specifically CHO-derived recombinant products, are manufacture.	
772	Case Category	Import (Saima Hussain)
	Name, address of Applicant.	My Body Healer (Private) Limited Office No. 104 & 105, 1st Floor, Plot No. 54-C, Al Murtaza Commercial Lane-2, Phase VIII, DHA, Karachi (670)
	Application Form Dy. No / Tracking ID & date of submission	(BV6-S4X-ABPP, 2026-03-16)

Detail of Fee Submitted	313500, 2025-12-10,
The proposed proprietary name / brand name	Bicutamide 50mg Tablets
Label Claim	Each film coated tablet contains: Bicalutamide ... 50mg
Reference to Finished product specifications	European Pharmacopeia
Proposed Pack Size	7's, 10's, 14's, 20's, 28's & 30's-Controlled
Shelf Life (Unit)	60 MonthStore below 30°C
For generic drugs (me-too Status)	Geperprost 50mg Tablets by Novartis Pakistan Ltd.
Pharmacotherapeutic Group of (API)	Anti-Androgens
Name, address of Manufacturing site:	Pharmacare Premium Ltd.-HHF003. Hal Far Industrial Estate, Birzebbugia, BBG3000, Malta.-Malta
Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Module III Section 3.2.P.2
Name, address of Marketing Authorization Holder:	My Body Healer (Private) Limited, Office No. 104 & 105, 1 st Floor, Plot No. 54-C, Al Murtaza Commercial Lane-2, Phase VIII, DHA, Karachi. , Pakistan
Details of Certificates (CoPP/FSC/cGMP):	GMP certificate of FP Manufacturer attached in Module I.
Details of Authorization Letter :	Not applicable for imported product
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Module III, section 3.2.S.7.
The status in reference regulatory authorities	Casodex 50mg Film-Coated Tablets, France ANSM

Evaluation Remarks

We, Pharmacare Premium Ltd., manufacturer of Bicutamide 50mg would like to justify the use of in-house method instead of adopting specification as per British Pharmacopeia (BP) or United States Pharmacopoeia (USP) for testing the finish product. Pharmacare Premium Ltd. is a pharmaceutical company based in Malta, Europe and therefore, the company primarily refers to European Pharmacopeia (Ph.Eur.) which does not have any monograph for Bicalutamide tablets. However, Bicalutamide API is tested according to Ph.Eur. monograph and relevant CEP. Furthermore, at the time when the formulation was developed, no pharmacopeial monograph was available for FP. For this reason, the FP manufacturer developed in-house analytical method, which are fully validated and validations are presented in section 3.2.P.5.3, demonstrating that the analytical method are suitable for their intended use. A comparison between the in-house specifications established by Pharmacare Premium Ltd. and the pharmacopoeia specifications described in BP and USP is presented below.

Test	Pharmacare	British Pharmacopoeia	USP
ID by IR	Complies with reference standard	IR spectrum of test product is concordant with the reference spectrum of bicalutamide	The UV spectrum of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay
ID by Retention Time	Complies with reference standard	In the Assay, the retention time of the principal peak in the chromatogram obtained with test solution is similar to that of principal peak in the chromatogram obtained with standard solution	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay

Assay	95.0%–105.0%	95.0%–105.0%	90.0%–110.0%
Related substance / Impurities	Max unknown impurities: 0.2% Total unspecified impurities: 0.5% Disregard any peaks less than 0.01% of the test solution concentration (LOD)	Imp. C: 0.15% Maximum unspecified impurities: 0.2% Total unspecified impurities: 0.7% Disregard any peak less than 0.1%	Bicalutamide Aminobenzonitrile: NMT 0.1%

Dissolution	NLT 80% (Q) in 30 min	NLT 75% (Q) in 45 min	NLT 80% (Q) in 45 min
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However, the dissolution method recommended by USP have dissolution medium 1.0% w/v sodium lauryl sulfate in water with rotating speed between 50-75rpm 1000 mL and BP Use Apparatus 2, rotating the paddle at 50 revolutions per minute. Use 900 mL of a 1.0% w/v solution of sodium dodecyl sulfate, at a temperature of 37°, as the medium, while the 2% Sodium Dodecyl Sulfate (SDS) Dissolve 20g of SDS in 1000mL of Purified Water. Allow to SDS to fully dissolve and the foam to dissipate with the rotating speed 100rpm.

Decision

Deferred

The case is deferred for confirmation of export of the same product from the same manufacturing site to any country of a stringent regulatory authority or to a country whose regulatory agency is included in the DRAP approved list of RRAs. OR Submit bioequivalence study data conducted against the reference/innovator product.

773	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Global Pharmaceuticals Pakistan Plot # 8, Street # S-8, RCCI, Industrial Estate Rawat, Islamabad-Pakistan (000724)
	Application Form Dy. No / Tracking ID & date of submission	(28E-AW2-8LVM, 2024-06-21)
	Detail of Fee Submitted	30000.0, 2024-05-06,
	The proposed proprietary name / brand name	DAP GEL 5%
	Label Claim	EACH GRAM CONTAINS: DAPSONE.....50MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 20–25°C (68–77°F); excursions permitted to 15–30°C (59–86°F)
	For generic drugs (me-too Status)	DAPSONE GEL 5% BY HUDSON PHARMA (PVT) LTD
	Pharmacotherapeutic Group of (API)	Sulfones Antibiotics J04BA02
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nuray Chemicals Private Limited ADDRESS: Plot No. 111, SIDCO Industrial Estate, Thiruvallur – 602 003. Tamilnadu, INDIA.

Detail of stability batches of drug product	stability data of three batches submitted
Documents for the procurement of API with approval from DRAP (in case of Import)	clearance certificate is submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE has performed against the comparator product Dapsone Hudson Pharma
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of drug substance as per zone-IV condition is submitted by the firm.
The status in reference regulatory authorities	USFDA
GMP status of the firm	GMP certificate issued in the name of Reliance Pharma dated August,2022 is attached
Evidence of approval of manufacturing facility	GMP certificate issued in the name of Reliance Pharma dated August,2022 mentioned that firm has cream/ointment section

Evaluation Remarks

S.no.	Observations	Response of the Firm
1.	Submit the minimum fill volume or target fill volume per tube, as the specification table mentioned that “meet the specification,” whereas the BMR indicates that an average of 3 g of gel per tube was filled for the trial batches. Additionally, justify the selected fill volume in comparison with the innovator’s marketed pack size, noting that the minimum tube size supplied by the innovator is 30 g.	Firm replied that ,as mentioned in BMR filled volume is 3g. Commercial sample 30g and professional sample 3g pack sizes are mentioned by innovator. We have manufactured trial batches therefore 3g pack size was followed. US FDA reference of pack size is attached.
2.	Provide reference to the relevant international guidelines that permit conducting stability studies on drug product batches filled in container volumes smaller than the intended commercial batch container size.	Firm replied that, across major regulatory frameworks, including ICH, FDA, and EMA, it is well established that stability studies may be conducted on reduced batch sizes or reduced fill volumes, provided that appropriate scientific justification is submitted. Reduced stability designs are acceptable for most under such complex delivery systems. however, additional justification is warranted for complex drug delivery systems where potential drug-device interactions may impact stability. The present product does not fall under such complex drug delivery systems. However, the ICH guidelines clearly mentioned that Stability studies should be performed on each individual strength and container size of the drug product unless bracketing or matrixing is applied.

Decision

Deferred

The Registration Board has decided to defer the instant application for the submission of following:

The firm should manufacture three trial batches using a target fill volume of 30 g per tube, consistent with the proposed commercial pack size. Stability studies must be conducted on these newly manufactured trial batches and accordingly, submit the stability data along with complete raw data sheets, chromatograms, and all other relevant supporting documents.

774	Case Category		New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.		Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission		(J32-G55-WX4J, 2026-02-03)
	Detail of Fee Submitted		38700, 2026-01-29,
	The proposed proprietary name / brand name		Dasani Tablet 20 mg
	Label Claim		Each film coated tablet contains: Dasatinib.....20mg.
	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,60's-As per SRO
	Shelf Life (Unit)		2 Year(s)store below 30°C in a cool and dry place
	For generic drugs (me-too Status)		Provided
	Pharmacotherapeutic Group of (API)		Multi kinase inhibitors (Anti-Cancer)
	Name, address of Manufacturing site:		Self Manufacturing
	Name & address of API manufacturer		
	Detail of stability batches of drug product		Accelerated Stability Study {0, 3 & 6 months(completed)}, Long term / Real time stability study {0, 3, 6, months (completed)}
	Documents for the procurement of API with approval from DRAP (in case of Import)		attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile		pharmaceutical equivalence and CDP has been provided,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		provided
	The status in reference regulatory authorities		Food & Drug administration (FDA)
	GMP status of the firm		valid
	Evidence of approval of manufacturing facility		attached
	Evaluation Remarks		
Sr.no.	Observations	Response of the firm	
1.	Clarify how the drug product manufacturer has performed particle size determination test while the quality analysis of drug substance, since the test result were mentioned on the batch analysis report of drug substance performed by drug product manufacturer.	Firm replied that the drug product manufacturer does not perform particle size determination testing at the manufacturing site. However, during incoming material evaluation and documentation review, the particle size determination results were incorporated in the drug substance Certificate of Analysis issued by the drug product	

		manufacturer based on the compliant results reported by the API manufacturer and verification of the same through the DMF review and manufacturer's COA.
2.	Justify for performing the dissolution test via UV method when the innovator product clearly mentioned in its literature that "HPLC with UV detector is used to quantify drug in the dissolution sample"	A detailed literature survey was conducted to identify suitable analytical procedures for the dissolution testing of Dasatinib tablets. Based on this survey, a validated UV spectrophotometric method reported in peer-reviewed literature was adopted for dissolution analysis. The referenced publication is attached for review. However, the reference literature is relevant to the quantification of API in tablet not the quantification of drug in the dissolution samples, further, according to the reference literature, at 232 nm dasatinib shows maximum absorption while applicant determined absorbance at 215nm.
3.	The Abs values in CDP and dissolution testing (stability) are around 0.4. Please justify that such low value of Absorbance can be significant for calculating concentration. Also how much lower the abs value can be in lower concentrations? wouldn't it be affected by noise of instrument? Submit Calibration curve being used in dissolutions and also submit UV spectrum of Dasatinib.	The submitted calibration curve does not correlate with the reported absorbance values, as the observed absorbance at the stated concentration deviates significantly from the value predicted by the calibration equation.
Decision		
Rejected		
The board deliberated on the matter that the absorbance range of calibration curves is between 0.4 to 1.2, whereas all the results of dissolution are around value of 0.4 (minimum value on calibration curve) and reported to indicate drug release of more than 95%. This contradiction of absorbance values of dissolution and calibration curve raises concern regarding genuineness of dissolution data. Due to this reason board rejected the case.		

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Case Category	Routine (Saima Hussain)	
Name, address of Applicant.	The Searle Company Limited 32-KM Multan Road, Lahore (000647)	
Application Form Dy. No / Tracking ID & date of submission	(BL8-ZUH-LPE1, 2024-03-12)	
Detail of Fee Submitted	75000.0, 2024-01-04,	
The proposed proprietary name / brand name	BILFAXIN 2.5mg/ml Oral Solution	
Label Claim	Each mL contains: Bilastine.....2.5 mg	
Reference to Finished product specifications	As per Innovators Specification	
Proposed Pack Size	as per DPC-As per SRO	
Shelf Life (Unit)	2 Year(s)Store below 30 C	
For generic drugs (me-too Status)	Not applicable	
Pharmacotherapeutic Group of (API)	Antihistamine	
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer	Lee Pharma Limited Address: Survey No. 10/G-1, Gaddapotharam (Village) Jinnaram (Mandal), Sangareddy (District) Telangana State - 502319, INDIA.	
Detail of stability batches of drug product	Stability data of batches (T001,T002,T003) 6 litre each	
Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP attested commercial invoice along with Form-6 is submitted.	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies has been performed against reference product Ilaxtinn syrup 2.5mg/ml manufactured at A. Menarini Farmaceutica	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV conditions are submitted	
The status in reference regulatory authorities	Approved by Health Canada with brand name of: BLEXTEN® 2.5mg/ml Oral Solution by Aralez Pharmaceutic	
GMP status of the firm	GMP Certificate dated 27-04-2021 is submitted by the firm.	
Evidence of approval of manufacturing facility	GMP Certificate dated 27-04-2021 confirms that firm has oral liquid section.	
Evaluation Remarks		
Sr.no.	Observations/Shortcomings	Response of the Firm
1.	It is observed that different assay methods for the drug substance have been applied by the drug product manufacturer and the drug substance manufacturer. The major differences between the two methods include the chromatographic mode (isocratic method by the drug product manufacturer and gradient method by the drug substance manufacturer), variations in mobile phase and diluent compositions, as well as	The assay method for the drug substance adopted by M/s The Searle Company Limited, was originally developed In-House in accordance with ICH Guideline Q2(R1) and the recommendations outlined in USP <1225>, the method underwent a comprehensive validation. Upon achieving satisfactory validation outcomes, the method was formally adopted for the determination and evaluation of the specified

	differences in the sample and standard preparation procedures. Justify the use of different assay methods for the same drug substance by the drug product manufacturer and the drug substance manufacturer.	active pharmaceutical ingredient (API). The detailed Validation Report is provided in Annexure 1 for your kind consideration.
2.	Please specify the reference considered for establishing the acceptance limit of pH for the oral solution, since the available literature for the innovator product approved by MHRA indicates that the pH of Ilaxten oral solution is maintained between 3.0 and 4.0.	The defined acceptance limits i.e 3.0-5.0 for the pH of the oral solution are established to ensure optimal antimicrobial activity and to support the efficacy of the preservatives incorporated in the formulation.
3.	Justify for not including the paraben content test in the finished product specification, despite the use of methyl paraben and propyl paraben as preservatives in the formulation.	To ensure the effectiveness of the preservatives used in our formulation, preservative efficacy testing was conducted by the The Searle company Limited. The corresponding Preservative Efficacy Report is provided in Annexure 2 for your kind consideration.
4.	Justify for not including the deliverable volume test in the finished product specification, although the test is recommended in official pharmacopeias for oral liquid dosage forms packaged in multiple-dose containers, in accordance with the requirements described in USP General Chapter <698> Deliverable Volume.	Deliverable volume testing is an integral part of the finalized Batch Manufacturing Record (BMR) and is a controlled parameter within the Quality Management System (QMS) prior to the commencement of commercial manufacturing. As the trial stability batches were prepared on a small laboratory scale using manual filling, this test was not included during the trial phase. It is important to note that deliverable volume is not considered a stability-indicating parameter. However, its evaluation was conducted prior to the initiation of stability studies, and the relevant data is available in the Certificates of Analysis (CoAs) from the initial testing stage.
5.	In-use stability studies of the opened bottles are required to be submitted along with the proposed in-use storage conditions and in-use shelf-life, as the innovator product approved by MHRA specifies a defined shelf-life for the oral solution after first opening.	In-use Stability studies of the opened bottles was conducted alongside the normal regular stability studies. In line with the recommendations provided by the innovator's reference in the MHRA , six-month post-opening stability study was performed.

Case was deferred in 353rd meeting for the submission of complete stability data of the drug product up to the claimed shelf life, for confirmation that the obtained pH values at each stability time point are within the revised specified limits. Firm submitted stability data of drug product till 24 months, in which the obtained pH values at each stability time points are within revised specified limits.

Decision

Approved

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

776	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	(QVM-H9B-HHE1, 2025-03-06)
	Detail of Fee Submitted	37000.0, 2024-10-29,
	The proposed proprietary name / brand name	Bemtec
	Label Claim	Each film-coated tablet contains: Bempedoic Acid.....180mg
	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 Year(s)Store below 30 degree centigrade
	For generic drugs (me-too Status)	Bempex 180mg Tablet
	Pharmacotherapeutic Group of (API)	Adenosine triphosphate-citrate lyase (ACL) inhibitor.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited
	Detail of stability batches of drug product	Stability data of batches 24PD120BPAS01, 24PD121BPAS02 , 24PD122BPAS03 2500tablets batch size each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 Computerized No: K-2582062662167 dated 26-Oct-2023 is submitted by the firm.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against Nilemdo 180 mg Tablet Bempedoic Acid 180 mg Tablet Batch No. 399412 24PD120BPAS01 Manufactured by Daiichi-Sankyo.
	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	Nilemdo 180mg Tablets (MHRA Approved)
	GMP status of the firm	GMP certificate dated 01st January, 2024 is submitted by the firm.
	Evidence of approval of manufacturing facility	GMP certificate dated 01st January, 2024 mentioned that firm has tablet (general) section.

Evaluation Remarks

The innovator literature indicates that the drug substance is freely soluble at pH greater than 6, but insoluble at pH 5 and below. However, according to the drug substance manufacturer's data, the substance is reported to be insoluble both below pH 5 and above pH 6, which contradicts the information provided by the innovator. Bempedoic acid is a weak dicarboxylic acid and the solubility of a weak acid is highly dependent on pH. Bempedoic acid is classified as a Biopharmaceutics Classification System (BCS) Class II drug, meaning it has low solubility and high permeability. Based on the request received, we reperformed the analysis of solubility in different pH buffer solutions and the results are tabulated below pH dependant solubility at about 37°C :

Phosphate buffer (pH 6.0): Very slightly soluble (0.3mg/mL) Phosphate buffer (pH 6.8): Slightly soluble (1.1mg/mL) Phosphate buffer (pH 8.0): Very slightly soluble (0.9mg/mL) Alkaline borate buffer (pH 10.0): Slightly soluble (1.0mg/mL) Based on results, minor differences are observed and it may be attributed to variations in synthetic routes and experimental conditions, which can influence the overall solubility profile of the drug substance. The technical report for quantitative solubility of bempedoic acid at 37°C has been provided. Case was deferred in 352nd meeting for submission of a justification from the drug substance manufacturer regarding the observed disparity between the solubility characteristics of the API supplied by M/s. Metrochem API Private Limited and those reported in the innovator literature of the USFDA. The firm shall submit the response along with the open part of the Drug Master File (DMF) of the drug substance, including detailed manufacturing procedure information. Firm in their reply stated that, Bempedoic acid solubility differences are due to variations in the synthetic routes and experimental conditions between Metrochem API Private Limited and the innovator. Its solubility profile is influenced by the fact that it is a weak dicarboxylic acid and it is a BCS Class II drug, meaning it has low solubility and high permeability. Based on the request received, we reperformed the analysis of solubility in different pH buffer solutions and shared the technical report for the quantitative solubility of Bempedoic acid. Phosphate buffer (pH 6.0): Very slightly soluble (0.3mg/mL) Phosphate buffer (pH 6.8): Slightly soluble (1.1mg/mL) Phosphate buffer (pH 8.0): Very slightly soluble (0.9mg/mL) Alkaline borate buffer (pH 10.0): Slightly soluble (1.0mg/mL) Further API manufacturer also shared the closed part of DMF providing the detailed manufacturing procedure of API.

Decision

Approved

777	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (000755)
	Application Form Dy. No / Tracking ID & date of submission	(NW6-5TD-4LEQ, 2024-05-22)
	Detail of Fee Submitted	75000.0, 2024-02-12,
	The proposed proprietary name / brand name	Combifen
	Label Claim	Each mL contains: Ibuprofen 9.6mg Paracetamol.....32mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100mL-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place. Below 30°C
	For generic drugs (me-too Status)	Nil
	Pharmacotherapeutic Group of (API)	Non-Steroidal Anti-inflammatory Drugs/ Analgesic and antipyretic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	PHARMAGEN LIMITED,ZENITH CHEMICAL INDUSTRIES (PVT.) LIMITED
	Detail of stability batches of drug product	Stability data of batches TF-01,TF-02,TF-02 of 500ml batch size each
	Documents for the procurement of API with approval from DRAP (in case of Import)	both API procured from local Manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE is performed against the Tachifereid 32mg/ml+9.6mg/ml Suspension of M/s. Angelini Pharma Spa.

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV condition is submitted by the firm.
	The status in reference regulatory authorities	Italian Medicines Agency (AIFA)
	GMP status of the firm	GMP certificate Certificate No. 48/2023-DRAP (K) dated 26th June, 2023. is submitted by the firm
	Evidence of approval of manufacturing facility	GMP certificate Certificate No. 48/2023-DRAP (K) dated 26th June, 2023 mentioned that firm has Oral Liquid (Syrup, Solutions & Suspension) (general) section.
Evaluation Remarks		
Registration Board in its 353rd meeting decided to defer the case for submission of relevant international guidelines in support of the conduct of initial stability studies on a 25 mL fill volume when the proposed commercial pack size is 100 mL. Firm in their reply stated that, with reference to the above observation regarding the conduct of initial stability studies on a 25 mL fill volume while the proposed commercial pack size is 100 mL, it is hereby clarified that the 25 mL. fill volume was filled and tested in a 25 mL bottle during trial batches testing; however commercial stability testing will be performed on proposed pack size of 100ml. we respectfully submit the following justification: In the present case: The container closure system for 25 mL and 100 mL. presentations is identical (same container material, closure type, and specifications). There is no change in formulation, manufacturing process, or primary packaging material. However, according to ICH guidelines Stability studies should be performed on each individual strength and container size of the drug product unless bracketing or matrixing is applied. Bracketing: The design of a stability schedule such that only samples on the extremes of certain design factors, e.g., strength, package size, are tested at all time points as in a full design. The design assumes that the stability of any intermediate levels is represented by the stability of the extremes tested. Where a range of strengths is to be tested, bracketing is applicable if the strengths are identical or very closely related in composition. Bracketing can be applied to studies of the same container closure system where either container size or fill varies while the other remains constant. However, if a bracketing design is considered where both container size and fill vary, it should not be assumed that the largest and smallest containers represent the extremes of all packaging configurations. Care should be taken to select the extremes by comparing the various characteristics of the container closure system that may affect product stability. These characteristics include container wall thickness, closure geometry, surface area to volume ratio, headspace to volume ratio, water vapour permeation rate or oxygen permeation rate per dosage unit or unit fill volume, as appropriate. Matrixing: The design of a stability schedule such that a selected subset of the total number of possible samples for all factor combinations is tested at a specified time point. At a subsequent time point, another subset of samples for all factor combinations is tested. Eg: oral solutions of different strengths with formulations that differ only in minor excipients (e.g., colourants or flavourings).		
Decision		
Deferred		
The Registration Board has decided to defer the instant application for the submission of following: The firm should manufacture three trial batches using a target fill volume of 100ml, consistent with the proposed commercial pack size. Stability studies must be conducted on these newly manufactured trial batches and accordingly, submit the stability data along with complete raw data sheets, chromatograms, and all other relevant supporting documents.		
778	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	NovaMed Pharmaceuticals(Pvt.)Ltd 28-KM Ferozepur Road Lahore (000590)
	Application Form Dy. No / Tracking ID & date of submission	(24Q-QEB-SYVP, 2024-10-31)
	Detail of Fee Submitted	37000.0, 2024-09-09,

The proposed proprietary name / brand name		Bempion
Label Claim		Each Film Coated Tablet Contains: Bempedoic acid.....180mg
Reference to Finished product specifications		As per Innovators Specification
Proposed Pack Size		10's , 20's 28's, 30-De-Controlled
Shelf Life (Unit)		2 Year(s)Store away from direct sunlight, heat and moisture below 30C
For generic drugs (me-too Status)		Nexletol tablet
Pharmacotherapeutic Group of (API)		Adenosine triphosphate-citrate lyase (ACL) inhibitor
Name, address of Manufacturing site:		Self Manufacturing
Name & address of API manufacturer		Lee Pharma Limited , Survey No. 10/G-1, Gaddapotharam (Village), Jinnaram (Mandal), Sangareddy (District), Telangana State - 502319, INDIA.
Detail of stability batches of drug product		Stability data of three batches of 2000 tablet each is submitted by the Firm
Documents for the procurement of API with approval from DRAP (in case of Import)		Firm taken loan from M/s.High Q
Pharmaceutical Equivalence and Comparative Dissolution Profile		PE and CDP have performed against the Nilemdo 180mg 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		Nexletol tablet 180mg
GMP status of the firm		Renewal of DML letter dated 14th September 2021 is submitted
Evidence of approval of manufacturing facility		Renewal of DML letter dated 14th September 2021 mentioned that firm has tablet section
Evaluation Remarks		
Sr.no.	Observations	Response of the Firm
1,	Clarify whether the API was procured through a loan from M/s. High-Q Pharmaceuticals or whether M/s. High-Q Pharmaceuticals imported the API on your behalf. Since the entire imported quantity of API has been reported as a loan provided to you by M/s. High-Q Pharmaceuticals, a clarification from both parties, i.e., the loan giver and the loan acceptor, is required in this regard.	Firm has only submitted tracking no. of intimation letter from M/s. High Q regarding the giving of Loan of API of 5kg.
Decision		
Approved		
Case Category		Routine (Saima Hussain)
Name, address of Applicant.		Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
Application Form Dy. No / Tracking ID & date of submission		(3GN-LTB-G358, 2024-10-08)
Detail of Fee Submitted		75000.0, 2024-09-20,
The proposed proprietary name / brand name		Fenone Tablet

	Label Claim	Each film-coated tablet contains: Finerenone.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	18's-As per SRO,30's-As per SRO,60's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	non-steroidal, selective mineralocorticoid receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	Stability data of three batches (batch size 1500,3000,3000) is submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	clearance certificate is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have performed against the innovator product Kerendia Tablet 20mg.
	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	FDA-USA (Kerendia Tablets 20mg)
	GMP status of the firm	GMP Certificate dated 3rd Sep,2024 is submitted
	Evidence of approval of manufacturing facility	GMP Certificate dated 3rd Sep,2024 mentioned that firm tablet (general) section
	Evaluation Remarks	
	Decision	
	Approved	
780	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	FRONTIER DEXTROSE LIMITED PLOT NO. 18/3 PHASE-1 INDUSTRIAL ESTATE HATTAR (000633)
	Application Form Dy. No / Tracking ID & date of submission	(5TZ-NPH-13JB, 2024-06-03)
	Detail of Fee Submitted	30000.0, 2024-04-29,
	The proposed proprietary name / brand name	Sterifluid NS 1/2 Infusion 500ml
	Label Claim	Each 100ml Contains: Sodium Chloride 0.45gm & Water for Injection..Q.s
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	500ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temperture
	For generic drugs (me-too Status)	Plabottle NISF NORMAIL SALINE Reg# 011252 Manufactured by Otsuka Pakistan Ltd.
	Pharmacotherapeutic Group of (API)	Electrolytes
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability data of three batches of 4000 bottles each is submitted by the firm

	Documents for the procurement of API with approval from DRAP (in case of Import)	clearance certificate is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE has performed against the comparator product Half Saline manufactured by Otsuka in 500ml.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies as per zone-iv condition is submitted by the firm,
	The status in reference regulatory authorities	SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER approved in USFDA link: https://www.accessdata.fda.gov/drugsatfda_docs/la
	GMP status of the firm	GMP certificate 15-12-2023 is submitted
	Evidence of approval of manufacturing facility	GMP certificate 15-12-2023 mentioned that firm has liquid injectable section (LVP)
	Evaluation Remarks	
	Decision	
	Approved	
	Firm shall submit fee for pre-registration variation as per the latest fee SRO prior the issuance of Registration letter.	
781	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan (000267)
	Application Form Dy. No / Tracking ID & date of submission	(JTQ-9QW-QEUV, 2024-10-07)
	Detail of Fee Submitted	75000.0, 2024-09-20,
	The proposed proprietary name / brand name	Fenone Tablet
	Label Claim	Each film-coated tablet contains: Finerenone.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	18's-As per SRO,30's-As per SRO,60's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	non-steroidal, selective mineralocorticoid receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	Stability data of three batches (batch size 1500,3000,3000) is submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	clearance certificate is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have performed against the innovator product Kerendia Tablet 10mg.
	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	FDA-USA (Kerendia Tablets 10mg)
	GMP status of the firm	GMP Certificate dated 3rd Sep,2024 is submitted
	Evidence of approval of manufacturing facility	GMP Certificate dated 3rd Sep,2024 mentioned that firm tablet (general) section

	Evaluation Remarks	
	Decision	
	Approved	
782	Case Category	Routine (Saima Hussain)
	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	(74B-TD5-PHYQ, 2024-10-03)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-13, 2024-09-25
	The proposed proprietary name / brand name	Tacor Ointment 0.03%
	Label Claim	Each gram contains: Tacrolimus (as monohydrate).....0.3mg (Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Eczemus Ointment 0.03%, Manufacturer: Brookes Pharma (Private) Limited
	Pharmacotherapeutic Group of (API)	immunosuppressant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability data of three batches 1500 tubes each is submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan of API has been taken from M/s. Valor
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE has performed against the ECZEMUS Ointment 0.03% of M/s. Brookes Pharma
	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	Tacrolimus Ointment 0.1%, Manufacturer: Accord Healthcare, New Drug Application (NDA): 211688, USFDA Approved
	GMP status of the firm	Issuance of DML letter dated 17th January,2024 submitted
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 17th January,2024 mentioned that firm has cream/ointment section
	Evaluation Remarks	
	Sr.no.	Response of the firm
	1.	Justify for not performing the system suitability parameter in accordance with USP monograph during the assay verification studies. The USP method mentioned a mixture of Tacrolimus working standard with impurities (Tacrolimus open ring and Tacrolimus 1-9 epimer), and Tacrolimus working standard alone during system suitability studies. As the DRAPexempted impurities testing in CTD submission, So the standards for impurities are not yet purchased from USP and the system suitability

		studies are performed using Tacrolimus working standard.
2.	Provide the evidence of reference product approved in RRA, using purified water as a solvent in tacrolimus ointment.	Purified water is not part of formulation of Tacor Ointment as mentioned in BMR. Revised formulation is submitted for your kind consideration.
Decision		
Deferred		
Deferred for the submission of revise assay verification studies of the drug substance in accordance with the USP monograph. The revise studies must include system suitability parameters as an integral part of the assay verification.		
783	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	M/s. Genix Pharma (Pvt) Ltd. Plot No 44-45-B, Korangi Creek Road, Karachi (000351)
	Application Form Dy. No / Tracking ID & date of submission	(3GE-DNG-RM4B, 2024-04-23)
	Detail of Fee Submitted	75000.0, 2024-04-03,
	The proposed proprietary name / brand name	Mesazine
	Label Claim	Each tablet contains: Mesalazine 1g
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-As per SRO
	Shelf Life (Unit)	24 Year(s) Do not store above 25°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Intestinal anti-inflammatory agent (ATC code: A07EC02)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Hengkang Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	Stability data of batches 23SB-422-01 (1500 tablets), 23SB-423-02 (1500 tablets), 23SB-424-03 (1500 tablets).
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have performed against the Pentasa 1g Prolong Release Tablet (B# 0635064) FERRING IRELAND LTD United Drug House, Magna Drive, Magna Business Park, Citywest Road Dublin 24, Ireland.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV condition is submitted by the firm
	The status in reference regulatory authorities	Pentasa 1 g prolonged-release tablets, Ferring Ireland Ltd
	GMP status of the firm	
	Evidence of approval of manufacturing facility	GMP certificate dated 13th June, 2023 mentioned that firm has tablet (general) section.
Evaluation Remarks		
	Sr. no	Shortcomings
		Response of the Firm

1.	Justify the application of BP specifications to the finished product, given that the procured API complies with USP specifications.	Mesalazine Prolong Release Tablet is not available in USP Monograph. furthermore, the API complies with USP specifications, the finished product has been developed and validated using BP specifications to maintain consistency with the analytical procedures and acceptance criteria established during product development. Both the API (USP-compliant) and the finished product (BP-compliant) meet internationally recognized compendial standards, ensuring the product's safety, efficacy, and quality remain uncompromised. Therefore, the application of BP specifications to the finished product does not impact product quality, safety, or efficacy.
2.	Justify the procedure adopted for performing system suitability during the assay verification of the drug substance, considering that the USP monograph specifies the requirement to confirm the resolution between 4-aminosalicylic acid and mesalamine, which should be not less than (NLT) 2.0.	We have updated our protocol as per the requirement. Revised protocol attached as Annex-I
3.	Justify for not including the LOD test while the quality analysis of drug substance by the drug product manufacturer	LOD test is already included in API COA & Specification. We hereby again submitted the COA & Specification as Annex-II
4.	Provide evidence of the reference product confirming that the approved formulation is classified as an uncoated product.	During the development of Mesalazine 1 g tablets, a thorough review of the reference product information and supporting documents was conducted. No details regarding film coating were identified, and all listed excipients corresponded to core tablet components only. The absence of any coating-related excipients confirms that the reference product is an uncoated tablet formulation. https://assets.hpra.ie/products/Human/23804/Licence_PA1009-006-

		007_21032025100650.pdf https://cima.aemps.es/cima/dochtml/ft/77022/FT_77022.html
5.	Provide the reference which has been used for setting the condition and acceptance criteria of dissolution test.	The dissolution test for Mesalamine Prolonged-Release 1 g Tablets has been developed in accordance with the British Pharmacopoeia (BP) monograph for Mesalazine Prolonged-Release Tablets, which states that “a suitable dissolution test is carried out to demonstrate the appropriate release of Mesalazine.” In line with this guidance, the dissolution conditions were selected based on the FDA Dissolution Database to ensure appropriate and scientifically justified testing parameters. Regarding the acceptance criteria, reference was made to the innovator product data, which indicates that the formulation provides drug release over a period of approximately 12 hours, corresponding to the elimination profile from systemic circulation. Therefore, a 12-hour prolonged-release dissolution specification has been established to reflect and simulate the in vivo release characteristics of the innovator product. BP Monograph is Attached.
6.	Later, firm claimed that As there is no specific dissolution method officially available in BP Monograph, reference was taken from the FDA Dissolution Database method for Mesalamine 1.2 g Delayed-Release Tablets, applying the same apparatus, rotation speed, dissolution medium, and temperature conditions to ensure relevance and alignment with existing regulatory expectations.	Firm replied that The optimized QC release points at 1, 4, 8 and 12 hours provide adequate control of early, mid and terminal release phases. Comparative dissolution profiling demonstrates a gradual release pattern comparable to the reference product. Hence, continued release up to 12 hours is consistent with the intended prolonged-release design of mesalazine formulations. However, the USFDA dissolution guideline for extended-release dosage form clearly stated that A minimum of three time points is recommended to set the specifications. These time points should cover the early, middle, and late stages of the dissolution profile. The last time point should be the time point where at least 80% of drug has dissolved. If the maximum amount dissolved is less than 80%, the last time point should be the time when the plateau of the dissolution profile has been reached.

Reference is attached. On the basis of their reference product which clearly indicates that the maximum drug release is achieved at approximately 6 hours, as the dissolution sampling is performed up to 8 hours. This is also confirmed from the innovator's Pentasa® 1.2 g delayed-release tablet literature, which specifies the recommended dissolution conditions and acceptance criteria as follows: USP Apparatus II at 100 rpm, using pH 1.0 HCl buffer for 2 hours, followed by pH 6.4 phosphate buffer for 1 hour, and pH 7.2 phosphate buffer with sampling at 1, 2, and 6 hours. So justify the adopted limit till 12 hours.

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| 7. Justify, how the assay method adopted by you is valid without including the system | We mistakenly overlooked the test therefore; we have revised our specification as per monograph. Updated Specification along with Deposited challan of Rs. 9,400/- having no. 7449006352 dated 12-11-2025 Attached |
|---|--|

	suitability parameter in the analytical procedure.	
8.	Submit valid GMP certificate of API manufacturer issued by the authorized issuing authority.	Valid GMP Certificate attached.

Registration Board in its 353rd meeting decided to defer the case for submission of references or method development studies to justify the acceptance limits adopted for the dissolution test of the applied product, as the submitted USFDA reference of mesalamine delayed-release tablets is not acceptable. Furthermore, the supporting justification should comply with the dissolution general chapter of the pharmacopeia and applicable international guidelines. Firm in its reply stated that We have performed the dissolution testing of all stability batches with the mentioned dissolution conditions and time points. The results found are also given belows: Dissolution medium: Phosphate buffer pH 6.8 Temperature: 37 °C Speed: 100 rpm Apparatus: USP Apparatus II Paddle Timepoints: 1 hr, 4 hrs, 8 hrs & 9 hrs The dissolution results across all stability batches demonstrated consistent and reproducible drug release behavior at each evaluated time point. At 8 hours, the average drug release was approximately 79–80%. At 9 hours, all three stability batches showed dissolution values greater than 90%. Therefore, the final dissolution time point has been revised to 9 hours, with an acceptance criterion of NLT 80%. Further, firm was asked that, According to the available literature on the official website HPRA,Ireland, the innovator product comprises ethylcellulose-coated granules compressed into a tablet, wherein the tablet rapidly disintegrates after administration to release intact, ethylcellulose-coated granules that subsequently control the drug release. In contrast, the applied formulation involves a simple physical blend of mesalazine with ethylcellulose, without the formation of coated granules prior to compression. Justify how the applied formulation can be considered equivalent to the innovator product. In their reply firm stated that, The proposed formulation is manufactured using wet granulation, which enables uniform distribution of ethyl cellulose around mesalazine particles during granule formation. The wet granulation process promotes adhesion of ethylcellulose onto drug particles, resulting in a matrix formation. Ethyl cellulose, being water-insoluble and hydrophobic, forms a diffusion barrier around drug particles. This matrix system provides comparable controlled drug release of Mesalazine. Therefore, despite differences in manufacturing approach, the two formulations are pharmaceutically and functionally equivalent, as supported by similar release characteristics.

Decision

Deferred

The case has been deferred for submission of evidence of reference product approved in RRA, that is manufactured by simple blending of the active pharmaceutical ingredient (API) with ethyl cellulose (polymer), rather than through the preparation of ethyl cellulose-coated granules prior to compression into tablets, as recommended by the innovator product Pentasa 1 g prolonged-release tablet.

784	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Pharmedic Laboratories (Pvt.) Ltd Lahore 16-Km Multan Road, Lahore (000228)
	Application Form Dy. No / Tracking ID & date of submission	(7MN-NHL-2HEQ, 2024-06-20)
	Detail of Fee Submitted	30000.0, 2024-06-12,

The proposed proprietary name / brand name		Sterile Water for Injection
Label Claim		Each 10 mL contains: Sterilized Water for Injection
Reference to Finished product specifications		British Pharmacopeia
Proposed Pack Size		10ml clear glass Pri-As per SRO
Shelf Life (Unit)		5 Year(s) Do not store above 30 C, store in the original package in order to protect from moisture.
For generic drugs (me-too Status)		Water for Injection of M/s Vision Pharma
Pharmaceutical Group of (API)		Water for injection
Name, address of Manufacturing site:		Self Manufacturing
Name & address of API manufacturer		
Detail of stability batches of drug product		Stability data of three batches of 1000 Ampoules batch size
Documents for the procurement of API with approval from DRAP (in case of Import)		NA
Pharmaceutical Equivalence and Comparative Dissolution Profile		.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		NA
The status in reference regulatory authorities		Sterilized Water for Injection (By Fresenius Kabi Deutschland Germany
GMP status of the firm		.
Evidence of approval of manufacturing facility		.
Evaluation Remarks		
Sr.no.	Observations	Response of the Firm
1.	Clarify the discrepancy between the manufacturing and testing timelines: the batch was filled on 20-10-2023, whereas the bulk analysis was performed on 24-10-2023. Furthermore, please explain how the filling of bulk into ampoules was initiated without prior QC release of the bulk material.	Firm replied that All stability batches were manufactured strictly in accordance with the manufacturing dates stated on their respective Certificates of Analysis (CoAs). Date 20-10-2023 appearing in the Summary of Trial Cards submitted to DRAP was the result of an inadvertent typographical error and does not reflect the actual manufacturing date of the concerned batch. It was basically trial card written date and also the date for dispensing of ampoules used in all 3 trials. In support of this clarification, the complete Trial Manufacturing Records (TMRs) for all three (03) stability batches have been enclosed for verification and confirmation and accordingly submitted the revised BMR.
Decision		
Approved		
Firm shall submit fee for pre-registration variation as per the latest fee SRO prior the issuance of Registration letter.		
785	Case Category	Contract Manufacturing (Saima Hussain)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)

	Application Form Dy. No / Tracking ID & date of submission	(1YQ-BXX-51WP, 2024-07-15)
	Detail of Fee Submitted	75000.0, 2024-06-27,
	The proposed proprietary name / brand name	Norista 5mg Tablet
	Label Claim	Each Uncoated Tablet Contains: Norethisterone (USP).....5mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	Postpon-M Tablet by OBS Karachi
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	Registration Board in its 352nd meeting approved the applied drug product in the name of M/s. Wnsfield Pharmaceuticals, 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 asan application for cross-reference of already approved data on Form 5F. Applicants need to submit adeclaration that they will adopt the same source of drug substance, drug product formulation,specifications and container closure and fulfill other conditions mentioned in the above-mentionednotification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is alsoneeded as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Firm shall submit fee for pre- registration variation as per the current Fee SRO prior the issuance of Registration Letter.	
786	Case Category	Contract Manufacturing (Saima Hussain)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(8ST-P8M-LL7X, 2024-06-27)
	Detail of Fee Submitted	75000.0, 2024-06-26,
	The proposed proprietary name / brand name	Norista 5mg Tablet
	Label Claim	Each Uncoated Tablet Contains: Norethisterone (USP).....5mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearstore below 25°c
	For generic drugs (me-too Status)	Postpon-M Tablet by OBS Karachi
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	

	Registration Board in its 352nd meeting approved the applied drug product in the name of M/s. Wnsfield Pharmaceuticals, 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 per the current Fee SRO prior the issuance of Registration Letter.	
787	Case Category	Contract Manufacturing (Saima Hussain)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(BRP-S11-DLM5, 2024-06-27)
	Detail of Fee Submitted	75000.0, 2024-06-26,
	The proposed proprietary name / brand name	Rozimibe 5mg + 10mg Tablet
	Label Claim	Each Film Coated Tablet contains: Rosuvastatin as Calcium Salt (USP).....5MG Ezetimibe (USP) 10MG (Product Complies Innovators Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year store below 25°C
	For generic drugs (me-too Status)	Rovista EZ 5mg+10mg Tablet by Getz Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	
	Evaluation Remarks Registration Board in its 352nd meeting approved the product in the name M/s. Wnsfield Pharmaceuticals, 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 per the current Fee SRO prior the issuance of Registration Letter.	
	Case Category	Routine (Saima Hussain)
788	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, 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.

Decision

Deferred

Deferred 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.

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	(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 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, as these documents were not	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.

	included in the pages referenced in your previous response.	
	Decision	
	Deferred	
	Deferred 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.	
790	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	S&K Pharmaceuticals Plot N0. 252, Sunder Industrial Estate (000961)
	Application Form Dy. No / Tracking ID & date of submission	(4Z8-Z2R-VXMS, 2025-03-18)
	Detail of Fee Submitted	37000.0, 2024-11-20,
	The proposed proprietary name / brand name	SK-MOL 1%
	Label Claim	Each 100mL contains: Paracetamol 1.0%w/v
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	Pacipar IV Infusion by Pacific Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Analgesic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pharmagen Pvt Ltd
	Detail of stability batches of drug product	Stability data of three batches of 100l each is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	API procured from M/s. Pharmagen
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE has performed against the brand Pacipar of M/s. Pacific Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of three batches has been submitted.
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	Firm submitted the issuance of DML letter dated 10th November,2022.
	Evidence of approval of manufacturing facility	Firm submitted the issuance of DML letter dated 10th November,2022 mentioned that Liquid Infusion (general) section.
	Evaluation Remarks	
	Sr.no.	Response of the Firm
	Observations	
	1.	The 2025 edition of the BP includes the monograph for paracetamol infusion. Please method along with only chromatograms as

	align the finished product specifications with the updated BP monograph and submit a performance report based on the revised specifications, as conducted during the next scheduled stability study of the drug product.	evidence of performance, dates mentioned on chromatograms are 15-07-2025.
2.	Please explain how the assay may be considered valid when system suitability was not properly performed. The supplied chromatogram shows only two solutions were run, whereas the British Pharmacopoeia requires three solutions to be analyzed. Moreover, BP expressly states that “the test is not valid unless, in the chromatogram obtained with solution (3), the resolution between the two principal peaks is at least 4.0.” Submit the raw data sheets and complete analytical record of all the test that has been performed after adopted the BP monograph.	The firm submitted a single chromatogram from a standard run, displaying both the internal standard peak and the principal analyte peak, along with an assay verification report. However, the submission did not include the complete set of raw data sheets or the full chromatographic data required as evidence of performing quality analysis of finished in compliance of BP.

Decision

Rejected

The reported data of water loss study and particulate contamination tests obtained during the stability study of instant product are identical/exactly same to the data presented in another previously approved application of different product of the same applicant. This raises significant concerns regarding data integrity at the applicant's end and due to this reason case was rejected.

791	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Pharma Lord (Pvt) Ltd 12-km Lahore Road Layyah (000774)
	Application Form Dy. No / Tracking ID & date of submission	(EJ8-7RM-SQ84, 2024-06-13)
	Detail of Fee Submitted	30000.0, 2024-02-21,
	The proposed proprietary name / brand name	T Dol
	Label Claim	Each capsule contains: Tramadol Hydrochloride 50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10's, 30's, 50's-As per SRO
	Shelf Life (Unit)	2 Year(s) Accelerated (40°C ± 2°C and 75% ± 5%RH) Real time (30°C ± 2°C and 65% ± 5%RH)
	For generic drugs (me-too Status)	Tramal 50mg Capsule (Tramadol Hcl)
	Pharmacotherapeutic Group of (API)	opioid agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name : Lucent Drugs Pvt. Ltd. Address : Sy. NO.:10, Gaddapotharam Jinnaram (Mdl.),Sanga Reddy-502319, Telangana
	Detail of stability batches of drug product	Stability data of three batches 01J22 70 Packs(1×10's) 01-09-22 08-24 02J22 70 packs(1×10's) 03-09-22 08-24 03J22 70packs(1×10's) 05-09-22 08-24
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm submitted clearance certificate

Pharmaceutical Equivalence and Comparative Dissolution Profile		PE and CDP have performed against the comparator product Tramal 50mg Capsule Manufacturer SEARLE PHARMA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Stability data of three batches has submitted
The status in reference regulatory authorities		MHRA
GMP status of the firm		GMP certificate dated 11-08-2022 is submitted
Evidence of approval of manufacturing facility		GMP certificate dated 11-08-2022 mentioned that firm has capsule section
Evaluation Remarks		
Sr.no.	Observations	Response of the Firm
1.	As per the BP monograph for Tramadol Capsules, the test is not considered valid unless the chromatogram obtained with solution (3) demonstrates a resolution of at least 3.0 between the peaks corresponding to impurity A and tramadol. Justify how the verification studies submitted were deemed valid in the absence of this required system suitability parameter. Furthermore, justify how the assay verification studies of the drug product were conducted prior to the manufacturing of the trial batches, given that the trial batches were manufactured in September 2022, whereas the verification studies were performed in August 2022.	As a finished dosage form manufacturer, the assay verification was conducted using a validated and verified compendial method, while impurity profiling of the API is controlled through supplier qualification and routine API COA review. Although BP system suitability using solution (3) was not performed during verification, adequate chromatographic performance had been demonstrated by tailing factor less than 1.5 and relative standard deviation less than 2.0 %.during method validation. Therefore, the verification results are considered reliable. The assay verification studies submitted were conducted prior to manufacturing trial batches in August 2022 as part of method verification activities prior to analysis of trial batches in September 2022.
2.	Justify how the assay test being valid without the performance of system suitability parameter as recommended by BP, while conducting the stability.	Firm replied that the system suitability as recommended by BP was not performed but adequate chromatographic performance was demonstrated by tailing factor less than 1.5 and relative standard deviation less than 2.0%. However, it is clearly mentioned in the assay testing of BP monograph of Tramadol Capsule that System suitability The test is not valid unless, in the chromatogram obtained with solution (3), the resolution between the peaks due to impurity A and tramadol is at least 3.0.
3.	Justify the resubmission of same stability data in which only the long-term storage condition has been revised from 25 °C /60 % RH to 30°C/65% RH.	Firm replied that Upon internal quality review, it was discovered that the stability data table for the Long-Term Storage Condition (30°C ± 2°C / 65% RH ± 5% RH) inadvertently contained data points from the 25°C ± 2°C / 60% RH ± 5% RH study. This occurred during the final compilation of the data intended for Climate Zone IVa alignment. All regulatory and quality personnel have undergone mandatory retraining to prevent future data mapping errors. For your kind

		reference stability data of the drug substance as per zone iv-a conditions is submitted.
Decision		
Rejected		
The Board, upon deliberation, emphasized that the integrity and authenticity of submitted information is a basic requirement for the fair proceeding. In light of the submission of falsified and edited stability data pertaining to the drug substances by the applicant, the Board decided to reject the case.		
792	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(EBZ-T3T-8AT4, 2024-08-13)
	Detail of Fee Submitted	75000.0, 2024-07-04,
	The proposed proprietary name / brand name	Fenrone
	Label Claim	Each film coated tablet contains: Finerenone.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s, 14s,20s, 28s,30-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store over 30°C. Protect from direct sunlight, heat & moisture
	For generic drugs (me-too Status)	Not applicable as it is NCE.
	Pharmacotherapeutic Group of (API)	nonsteroidal mineralocorticoid receptor antagonist.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Lianyungang Jari Pharmaceutical Co.Ltd
	Detail of stability batches of drug product	Stability data of three batches 4000 tablet each is submitted (Mfg date : Jan-2024)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have performed against the innovator product Kerendia 20mg Tablet of M/s. Bayer., Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of three batches is submitted
	The status in reference regulatory authorities	Kerendia 20mg Tablet , Bayer AG Germany
	GMP status of the firm	GMP certificate dated 15th June, 2023 is submitted
	Evidence of approval of manufacturing facility	GMP certificate dated 15th June, 2023 mentioned that firm has tablet general section
Evaluation Remarks		
Decision		
Approved		
793	Case Category	Routine (Saima Hussain)

	Name, address of Applicant.	AGP Limited B-23-C, S.I.T.E., Karachi (000348)
	Application Form Dy. No / Tracking ID & date of submission	(M8B-TLE-X3DL, 2024-07-18)
	Detail of Fee Submitted	75000.0, 2024-07-04,
	The proposed proprietary name / brand name	Fenrone
	Label Claim	Each Film coated Tablet Contains: Finerenone----- -----10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s, 14s,20s, 28s,30-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store over 30°C. Protect from direct sunlight, heat & moisture
	For generic drugs (me-too Status)	Not applicable as it is NCE.
	Pharmacotherapeutic Group of (API)	nonsteroidal mineralocorticoid receptor antagonist.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Lianyungang Jari Pharmaceutical Co.Ltd
	Detail of stability batches of drug product	Stability data of three batches 4000 tablet each is submitted (Mfg date : Jan-2024)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have performed against the innovator product Kerendia 10mg Tablet of M/s. Bayer., Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of three batches is submitted
	The status in reference regulatory authorities	Kerendia 10mg Tablet , Bayer AG Germany
	GMP status of the firm	GMP certificate dated 15th June, 2023 is submitted
	Evidence of approval of manufacturing facility	GMP certificate dated 15th June, 2023 is submitted
	Evaluation Remarks	
	Decision	
	Approved	
794	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(DH3-6N6-NDPB, 2024-06-25)
	Detail of Fee Submitted	30000.0, 2024-06-20,
	The proposed proprietary name / brand name	Picrol Cream 1%
	Label Claim	Each gram of cream contains: Pimecrolimus.....10mg
	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 25C

For generic drugs (me-too Status)	Elidel by Contract Pharmaceutical
Pharmacotherapeutic Group of (API)	Topical calcineurin inhibitors (TCIs).
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	1.0% w/w PMAc T1-21 125 Tubes 1 x 1's Alu tube with plastic cap packed in unit carton 1.0% w/w PMAc T2-21 125 Tubes 1 x 1's Alu tube with plastic cap packed in unit carton 0, 3, and 6 months 1.0% w/w PMAc T3-21 125 Tubes 1 x 1's Alu tube with plastic cap packed in unit carton 0, 3, and 6 months
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm submitted DRAP attested commercial invoice
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE has performed against the Elidel Cream 1% of contract Pharmaceuticals, Canada
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	Elidel Cream by Contract Pharmaceutical Limited (FDA approved)
GMP status of the firm	GMP certificate dated 30-06-2022 is submitted
Evidence of approval of manufacturing facility	GMP certificate dated 30-06-2022 mentioned that firm has cream/ointment section

Evaluation Remarks

Sr.no.	Observations	Response of the Firm
1.	Clarify the manufacturing area in which the applied formulation will be manufacture i.e., whether it is manufactured in a general cream/ointment manufacturing section or in a dedicated/segregated section for creams/ointments, considering that the product is an immunosuppressant. Submit your response with an international reference in support of your reply.	We would like to submit that Pimecrolimus cream manufacturing can generally be performed in a general (multi-product) cream section, provided that a robust, science-based risk assessment is conducted to prevent cross-contamination. While pimecrolimus is a potent topical calcineurin inhibitor (TCI), it is typically manufactured in multiproduct facilities that adhere to WHO-GMP and ISO standards, rather than requiring a fully segregated, dedicated building, assuming proper containment strategies are in place. Regulatory bodies that generally allow the manufacturing of topical, non-steroid products like pimecrolimus in shared, controlled facilities include: FDA (U.S. Food and Drug Administration): Regulates under 21 CFR § 211, allowing shared facilities if cross-contamination is prevented by design. EMA (European Medicines Agency): Allows

		shared facilities based on a risk assessment and setting health-based exposure limits (PDEs). WHO (World Health Organization): GMP guidelines allow multiproduct facilities with proper segregation.
Decision		
Approved		
795	Case Category	Import (Saima Hussain)
	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	(B5X-GYP-1J5S, 2025-06-02)
	Detail of Fee Submitted	300000.0, 2024-10-25,
	The proposed proprietary name / brand name	CetroART
	Label Claim	Each Vial contains: Cetrorelix... 0.25 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's -As per SRO
	Shelf Life (Unit)	2 Year2-8 C
	For generic drugs (me-too Status)	Cetrotide 0.25mg injection
	Pharmacotherapeutic Group of (API)	Gonadotropin-releasing Hormone Antagonists
	Name, address of Manufacturing site:	Varian Pharmed-Plot 1534 2nd Golshid St, 2nd Golrokh St, West Ghazali Blvd. Eshtehard Industrial Town, Alborz, Iran-Iran
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Name, address of Marketing Authorization Holder:	Genome Pharma, RCCI Industrial Estate, Plot No. C-19, Access Road, Rawat, Islamabad., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Attached
	Details of Authorization Letter :	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	Cetrotide 0.25mg injection
	Evaluation Remarks	
	Firm submitted the free sale certificate dated 14/11/2024 mentioned that the product Cetrorelix (as Acetate) 250 mcg (brand CetroArt) is marketed in Islamic Republic of Iran since 22/05/2022. Firm submitted CoPP Ref: 665/759 Date: 5/4/2025 Address of the certifying authority: Division of Drugs and Controlled Materials Food and Drug Administration Ministry of Health Tehran, Iran Firm has not submitted the letter of Authorisation.	
	Sr.no.	Response of the Firm
	1.	Firm replied that, we performed a pharmaceutical equivalence assessment by analyzing the innovator product Cetrotide® in our laboratory and comparing its critical quality attributes with our product CetroART®.A complete Certificate of Analysis (COA) was generated for both the reference product and our test product. The COAs

		of Cetrotide® and COAs of CetroART® are attached.
2.	Provide a scientific justification for performing lyophilization on the bulk injectable solution prior to filling, instead of conducting lyophilization after filling into vials, as practiced by the innovator product.	Firm submitted a revised manufacturing procedure only change one step in the previous submitted manufacturing procedure i.e. Then, transfer the filtered solution to liquid filling machine. Calculate the sufficient amount of liquid according to assay result to equivalent 0.25 mg cetrotide. and fill 1.1 times the calculated liquid volume as overfill into each vial. Vials transfer to freeze dryer. 9. Freeze samples at -30° C for 4 hours.10. In primary drying apply the vacuum to 0.15 millibar for 24 hours.11. In secondary drying increase the vacuum to 0.06 millibar for a further 53 hours Manufacturing procedure has not included the step of stoppering prior keep in freeze dryer, further same lyophilization condition has kept both for bulk as prior submitted and filled ampoule, both documents seems to be same
4.	Submit documentary evidence demonstrating that the reference product approved by a Stringent Regulatory Authority (SRA) in which Water for Injection (WFI) is packaged in ampoule as a diluent instead of a prefilled syringe, as used in the innovator product.	Firm replied that, ASPORELIX 0.25 mg is an injectable product containing 0.25 mg of Cetrotide (as acetate). It is approved by the European Medicines Agency, and its diluent, Water for Injection (WFI), is packaged in an ampoule, similar to our product. However the submitted reference can not be verified from the official of ema.
Decision		
Deferred		
Case has deferred for submission of following shortcomings:		
Submit valid and legalized letter of Authorization pertaining to the applied product.		
Submit current batch manufacturing record of those batches which are manufactured using the revised manufacturing method.		
796	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(95W-DWG-AQPD, 2025-11-25)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Flor 25% Oral Solution
	Label Claim	Each 100ml Contains: Florfenicol 25gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Vetzflor 25% Oral Liquid by M/s Vetz Pharmaceuticals.

	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
797	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(9QW-UTH-QRW5, 2026-01-09)
	Detail of Fee Submitted	38700, 9400 2026-01-08, 2026-03-09
	The proposed proprietary name / brand name	Darvicox Liquid
	Label Claim	Each 100ml contains Norfloxacin USP.....2Ogm Guaifenesin USP.....2Ogm Aminophylline USP.....8gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Norammin-G Liquid Reg # 044976 (Leads pharma)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
798	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(ADV-GZ1-GED7, 2025-11-25)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Flor 23% Oral Solution
	Label Claim	Each 100ml Contains: Florfenicol 23gm
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Florvit 23% Oral Solution by M/s Vetz Pharmaceutical
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
799	Case Category	Import (Sara Mehreen)
	Name, address of Applicant.	Mian Traders Railways Road, Morre Eminabad (09-341-0135-118497D)
	Application Form Dy. No / Tracking ID & date of submission	(DJ2-WUE-8SSR, 2025-12-31)
	Detail of Fee Submitted	313500, 2025-12-24,
	The proposed proprietary name / brand name	GENTAMYCIN INJECTION
	Label Claim	Each ml contains: Gentamicin sulfate 100 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	Pack 1 amber glass bottle of 100 ml, 50 ml, 250 ml and plastic can of -De-Controlled
	Shelf Life (Unit)	36 Year(s)Store in shade and dry place, temperature below 30oC.
	For generic drugs (me-too Status)	Gantasin 10% Injection (100ml) of M / s Univet Pharmaceuticals, Rawalpindi. (Reg.No. 112219)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Asia Animal Pharmaceutical Co., Ltd-130, 1A National Road, Ba Lang ward, Cai Rang District, Can Tho city, Viet Nam-Vietnam
	Name, address of Marketing Authorization Holder:	MIAN TRADERS, GUJRANWALA, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	FREE SALE CERTIFICATE mentions that product CAN BE sold freely in Viet Nam and oversea markets.	
	Decision	

	Deferred	
	Deferred for confirmation of Free Sale Status in country of origin.	
800	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	(LDS-PHM-LAQG, 2025-07-12)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	STR-Acetyl-C Plus Powder
	Label Claim	Each 1000 gm contains: Acetylsalicylic Acid BP.....222gm Ascorbic Acid BP.....666gm (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,1kg-De-Controlled,250g-De-Controlled,2kg-De-Controlled,3kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Keep away from heat, moisture & children.
	For generic drugs (me-too Status)	Bio ASPI C Water soluble powder
	Pharmacotherapeutic Group of (API)	Analgesic, Antipyretic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 08.06.2023.
	Evidence of approval of manufacturing facility	
801	Evaluation Remarks	
	Decision	
	Approved	
801	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	(RP9-7V5-9P44, 2025-01-14)
	Detail of Fee Submitted	37000.0, 9400 2025-01-10, 2026-03-04
	The proposed proprietary name / brand name	LIPROCIN Oral Powder
	Label Claim	Each Kg contains: Lincomycin HCl USP..... 75gm Spiramycin BP..... 25gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10kg -De-Controlled,1kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	Sparcin Water Soluble Powder Reg. No.099301 (M/S My Lab (Pvt.) Ltd. Bahawalpur)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--

	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
802	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Attabak Pharmaceutical Industries 5-C Industrial Area I-10/3 Islamabad (000552)
	Application Form Dy. No / Tracking ID & date of submission	(SH6-AYH-PW5R, 2026-01-09)
	Detail of Fee Submitted	38700, 2026-01-08,
	The proposed proprietary name / brand name	Florobak plus Oral Liquid
	Label Claim	Each 100 ml contains Florfenicol 23gm Colistin sulphate BP.....50MIU (As Per Innovator 's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml- De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	FENICOL LIQUID UNIVET Reg #079134
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
803	Case Category	Import (Sara Mehreen)
	Name, address of Applicant.	ALASAR 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	(3DG-GJ2-BJEM, 2025-12-21)
	Detail of Fee Submitted	313500, 2025-12-18,
	The proposed proprietary name / brand name	Vimeflocol 23%
	Label Claim	Each ml contains : Florfenicol-----230mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 LTR -De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30C at dry place
	For generic drugs (me-too Status)	Florum 23% oral liquid
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	VEMEDIM ANIMAL HEALTH-SONG HAU INDUSTRIAL ZONE DONG PHU COMMUNE

		CHAU THANH DISTRICT HAU GIANG PROVINCE -Vietnam
	Name, address of Marketing Authorization Holder:	VEMEDIM ANIMAL HEALTH, SONG HAU INDUSTRIAL ZONE DONG PHU COMMUNE CHAU THANH DISTRICT HAU GIANG PROVINCE , Vietnam
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	FSC states that product CAN BE freely sold in Viet Nam and oversea markets.	
	Decision	
	Deferred	
	Deferred for confirmation of FREE SALE STATUS IN COUNTRY OF ORIGIN.	
804	Case Category	Contract Manufacturing (Sara Mehreen)
	Name, address of Applicant.	AUSPEC PHARMACEUTICALS PVT LTD 21, Km, Raiwind Road, Lahore. (000964)
	Application Form Dy. No / Tracking ID & date of submission	(VZG-SE2-41PH, 2024-04-23)
	Detail of Fee Submitted	75000.0, 2024-02-06,
	The proposed proprietary name / brand name	Ceph-P 500mg Injection
	Label Claim	Each vial contains: Cefepime as Hydrochloride (with L-arginine) 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's / DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C
	For generic drugs (me-too Status)	Pimestar Injection 500mg ByAulton Pharmaceutical, Hattar
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Aulton Pharmaceuticals.-Plot # 84/1, Block A, Phase 5, Industrial Estate, Hattar, Pakistan-
	Name & address of API manufacturer	M/s KOPRAN RESEARCH LABORATORIES LIMITED By K4/4, ADDITIONAL. M.I.D.C. AT & POST BIRWADI, TAL. MAHAD, DIST RAIGAD-402 302 MAHARASHTRA. INDIA.
	Detail of stability batches of drug product	Firm provided stability studies data on three batches (C274, C288, C306) as per zone IV A conditions.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Manufacturer provided copy of invoice of import of 10 kg Sterile Cefepime (HCL) with Arginine USP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm provided stability studies data on three batches (CEIV/B1203011, CEIV/B1203012, CEIV/B1203013) as per zone IV A conditions.
	The status in reference regulatory authorities	Maxipime 500mg Powder for Solution for Injection or Infusion By Hospira, Inc. Lake Forest, IL 60045

	GMP status of the firm	Certificate of cGMP was granted to firm on 04.06.2021.
	Evidence of approval of manufacturing facility	Manufacturer has Dry Powder Injection Section (Cephalosporin) vide letter no. F.1-17/2013-Lic dated 11.04.2017.
	Evaluation Remarks	
	Decision	
	Approved	
805	Case Category	Routine (Sara Mehreen)
	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	(5BM-2TM-PJRJ, 2024-05-15)
	Detail of Fee Submitted	30000.0, 2024-04-02,
	The proposed proprietary name / brand name	CALTRIM-H CREAM
	Label Claim	Each gram of cream contains: Clotrimazole USP.....10mg Hydrocortisone (as Acetate) USP.....10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)25°C
	For generic drugs (me-too Status)	Hydrozole Cream By M/s GSK Pharma Pakistan
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Firm provided stability studies data of 6 months for three trial batches manufactured.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm provided documents including invoices and drug import license for import of drug substances.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm provided pharmaceutical equivalence data with Hydrozole Cream.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Canesten HC Cream By Bayer Limited
	GMP status of the firm	Firm was granted GMP certificated dated 02.03.2021.
	Evidence of approval of manufacturing facility	Firm has cream/ointment/lotion section (General) granted vide letter No. F.3-6/2005-Lic(Vol-I) dated 17.1.2019.
	Evaluation Remarks	
	Decision	
	Approved	
806	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Magns Pharmaceuticals Plot # 7B Value Addition City Sahianwala Road Khurrianwala (000849)

	Application Form Dy. No / Tracking ID & date of submission	(L16-VTQ-32YJ, 2024-04-22)
	Detail of Fee Submitted	30000.0, 2024-03-07,
	The proposed proprietary name / brand name	Dermafin
	Label Claim	Each tablet contains: Terbinafine as HCl 125 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x10,s -As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30 oC
	For generic drugs (me-too Status)	Terbisil tablet
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Tagoor Laboratories Pvt., Limited (UNIT-I) Sy No.:29, Tupakulagudem, Pochavaram panchayat, Tallapudi (M), West Godavari Dist, Andhra Pradesh - 534341. Tel: 08813522860
	Detail of stability batches of drug product	Firm provided stability studies data of 6 months for three trial batches manufactured.
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has not provided comparative dissolution profile as per approved guidelines.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Lamisil tablet by Novartis FDA approved
	GMP status of the firm	GMP certificate was issued to firm dated 13.04.2022
	Evidence of approval of manufacturing facility	Firm has Tablet Sectio (General)
	Evaluation Remarks	
	Initially firm provided comparative dissolution studies data conducted on 6 units. Firm was informed that for the dissolution profile of test product and the innovator / reference product 12 units of each are required as per approved guidelines. In reply they provided dissolution data conducted on additional 6 tablets of same batch on which initial studies were conducted. However, it was observed that batch (additional 6 tablets) on which dissolution study was conducted, has expired on 05/2025 while additional studies were conducted on 09/2025 as per data provided by firm.	
	Decision	
	Rejected	
	Initially firm provided comparative dissolution studies data conducted on 6 units. Firm was informed that for the dissolution profile of test product and the innovator / reference product 12 units of each are required as per approved guidelines. In reply they provided dissolution data conducted on additional 6 tablets of same batch on which initial studies were conducted. However, it was observed that batch (additional 6 tablets) on which dissolution study was conducted, has expired on 05/2025 while additional studies were conducted on 09/2025 as per data provided by firm.	
807	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(YWS-TZ8-HQ88, 2024-12-20)

	Detail of Fee Submitted	30000.0, 7000.0 2024-07-02, 2024-11-05
	The proposed proprietary name / brand name	REACT EC 50MG TABLETS
	Label Claim	Each Enteric coated tablet contains; Diclofenac sodium.....50mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	3x10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Voltral 50mgTablets
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Firm submitted stability studies data of 6 months conducted on three trial batched manufactured.
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm provided pharmaceutical equivalence & comparative dissolution profile.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Dicloflex 50mg Tablet (Registered inUnited Kingdom.)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has Tablet Section (General) vide letter dated 17.01.2024.
	Evaluation Remarks	
	Decision	
	Approved	
808	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(DPU-YSB-QP19, 2024-12-20)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-02, 2024-11-05
	The proposed proprietary name / brand name	REACT SR 100MG TABLETS
	Label Claim	Each Film coated tablet contains; Diclofenac sodium.....100mg In sustained release formulation (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	3x10's -As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Voltral SR 100mgTablets
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Firm submitted stability studies data of 6 months conducted on three trial batched manufactured.

	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm provided pharmaceutical equivalence & comparative dissolution profile.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Diclofenac sodium 100mg Tablet(USFDA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has Tablet Section (General) vide letter dated 17.01.2024.
	Evaluation Remarks	
	Decision	
	Approved	
809	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(N1P-64G-5H9A, 2024-07-08)
	Detail of Fee Submitted	30000.0, 2024-05-29,
	The proposed proprietary name / brand name	Vetram 750mg Film Coated Tablets
	Label Claim	Each Film Coated Tablet Contains Levetiracetam USP.....750mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Xeticam 750mg Tablets, Manufacturer: Getz Phrama (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Firm submitted stability studies data of 6 months conducted on three trial batched manufactured.
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm provided pharmaceutical equivalence & comparative dissolution profile.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Levetiracetam 750mg Tablets, Manufacturer: Camber Pharmaceuticals Inc. (Registered in United States)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has Tablet Section (General) vide letter dated 17.01.2024.
	Evaluation Remarks	
	Decision	

	Approved	
810	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(897-GQR-M26A, 2024-08-16)
	Detail of Fee Submitted	75000.0, 2024-07-27,
	The proposed proprietary name / brand name	Pritam 250mg tabs
	Label Claim	Each Film Coated Tablet Contains; Levetricetam. 250mg (USP Spec"s)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30 ° C
	For generic drugs (me-too Status)	Xeticam 250mg Tablets Manufacturer: Getz Phrama (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd,-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	Name & address of API manufacturer	M/S: Hebei Renhe Yikang Pharmaceutical, Ltd. Address: Haixing Road, Zhao County Industrail Park
	Detail of stability batches of drug product	Firm provided 6 months stability studies data of three trial batches manufactured.
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm provided pharmaceutical equivalence & comparative dissolution profile data.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Levetiracetam Mylan 250mg Tablets , Mylan Pharamceuticals, Inc.,United States
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has Tablet Section (Geneal).
	Evaluation Remarks	
	Decision	
	Approved	
811	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(9BA-DXZ-LA1P, 2024-08-27)
	Detail of Fee Submitted	75000.0, 2024-07-27,
	The proposed proprietary name / brand name	Pritam 500mg tabs
	Label Claim	Each Film Coated Tablet Contains; Levetricetam USP..... 500mg (USP Spec"s)
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30 ° C
	For generic drugs (me-too Status)	Xeticam 500mg Tablets Manufacturer: Getz Phrama (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd,-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	Name & address of API manufacturer	M/S: Hebei Renhe Yikang Pharmaceutical, Ltd. Address: Haixing Road, Zhao County Industrail Park
	Detail of stability batches of drug product	Firm provided 6 months stability studies data of three trial batches manufactured.
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm provided pharmaceutical equivalence & comparative dissolution profile data.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Levetiracetam Mylan 500mg Tablets , Mylan Pharamceuticals, Inc.,United States
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has Tablet Section (Geneal).
	Evaluation Remarks	
	Decision	
	Approved	
812	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(7VB-RH8-973W, 2024-08-13)
	Detail of Fee Submitted	30000.0, 2024-07-11,
	The proposed proprietary name / brand name	Levita 500mg/5ml Injection
	Label Claim	Each 5ml Ampoule contains Levetiracetam 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store at 15°C to 30°C.
	For generic drugs (me-too Status)	Lerace 500mg/5ml Injection of M/s Hilton Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name: Shangyu Jingxin Pharmaceutical Co., Ltd. Site Address: No. 31 Weisan Road, Hangzhou Bay Shangyu Economic and Technological Development Area, Zhejiang Province, China
	Detail of stability batches of drug product	Firm provided stability studies data of three trial batches manufactured.

	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm provided Drug Import License for import of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm provided Pharmaceutical Equivalence Data.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	KEPPRA Injection of UCB, Inc. Smyrna, GA 30080 USA approved by USFDA
	GMP status of the firm	GMP certificate issued to firm dated 27.9.2023.
	Evidence of approval of manufacturing facility	As per GMP certificate firm has Parenteral (non-biopharmaceutical product).
	Evaluation Remarks	
	Decision	
	Approved	
813	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Aspin Pharma Plot # 10 & 25 Sector 20 Korangi Industrial Area Karachi 74900 Pakistan (000045)
	Application Form Dy. No / Tracking ID & date of submission	(561-V17-PV3U, 2024-08-19)
	Detail of Fee Submitted	30000.0, 2024-07-04,
	The proposed proprietary name / brand name	Gastasid 40mg Tablet
	Label Claim	Each Enteric coated tablet contains; Pantoprazole sodium USP eq. to pantoprazole..... 40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C.
	For generic drugs (me-too Status)	Zentro 40mg Tablets
	Pharmacotherapeutic Group of (API)	Antacid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NOSCH LABS PVT.LTD Survey No. 14, Gaddapotharam (Village), IDA, Kazipally, Jinnaram Mandal, Sangareddy District, Telangana-502 319. INDIA.
	Detail of stability batches of drug product	Firm provided 6 months stability data of three trial batches manufactured.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm provided API borrowing document from another local manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm provided pharmaceutical equivalence & comparative dissolution data.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Protonix 40mg Tablet
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has Tablet (General) Section vide letter dated 16.6.2021.
	Evaluation Remarks	
	Decision	

	Approved	
814	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Aspin Pharma Plot # 10 & 25 Sector 20 Korangi Industrial Area Karachi 74900 Pakistan (000045)
	Application Form Dy. No / Tracking ID & date of submission	(HAA-JQ8-NSGR, 2024-08-19)
	Detail of Fee Submitted	30000.0, 2024-07-04,
	The proposed proprietary name / brand name	Gastasid 20mg Tablet
	Label Claim	Each Enteric coated tablet contains: Pantoprazole sodium USP eq. to pantaprazole 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C.
	For generic drugs (me-too Status)	Zentro 20mg Tablets
	Pharmacotherapeutic Group of (API)	Antacid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NOSCH LABS PVT.LTD Survey No. 14, Gaddapotharam (Village), IDA, Kazipally, Jinnaram Mandal, Sangareddy District, Telangana-502 319. INDIA.
	Detail of stability batches of drug product	Firm provided 6 months stability studies data for three trial batches manufactured.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm provided API borrowing data from another local manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm provided pharmaceutical equivalence and comparative dissolution profile data.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Protonix 20mg Tablet
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has Tablet Section (General) vide letter dated 16.6.2021.
	Evaluation Remarks	
	Decision	
	Approved	
815	Case Category	Import (Sara Mehreen)
	Name, address of Applicant.	Minaa Medicos MR 127- 128, SHOP NO. 15, KATCHI GALI NO.2, MARRIOT ROAD, Karachi South Lyari Town (0152)
	Application Form Dy. No / Tracking ID & date of submission	(TZL-SRT-W2ND, 2025-11-07)
	Detail of Fee Submitted	313500, 2025-11-05,
	The proposed proprietary name / brand name	AMOXYHOPE LA
	Label Claim	Each ml contains: Amoxicillin Trihydrate 150mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	3 Year(s)Do not store above 25°C. Protect from light.
	For generic drugs (me-too Status)	REGISTRATION NO. 125652 AMOXI 15% INJECTION
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	M/s.Hebei Hope Harmony Pharmaceutical Co.,ltd-Industry Development Area Yuanshi County,Shijiazhuang City,Hebei Province,People's Republic of China-China
	Name, address of Marketing Authorization Holder:	M/s.Hebei Hope Harmony Pharmaceutical Co.,ltd, Industry Development Area Yuanshi County,Shijiazhuang City,Hebei Province,People's Republic of China, China
	Details of Certificates (CoPP/FSC/cGMP):	Firm submitted copy of apostilled GMP certificate issued by Deptt. of Agriculture & Rural Affairs of Hebei Province, China.
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Case was deferred in 356th meeting of the Registration Board for verification of dedicated manufacturing facility for Penicillin. Minutes of said meeting were communicated to firm. Firm replied as following: "With reference to the observation of the Registration Board regarding verification of dedicated manufacturing facility, we hereby submit the undertaking and supporting documents provided by the manufacturer for Amoxyhope (Amoxicillin Injection 15%). It is submitted that the above-mentioned product is manufactured in a dedicated Penicillin (β-lactam) facility, i.e., Workshop 204, with a separate injection production line. Although the facility is located within the same building structure, it is established on a separate floor with completely independent HVAC systems, utilities, personnel flow, and material flow, ensuring full compliance with cGMP requirements and prevention of cross-contamination. Supporting documents including site layout, production layout, undertaking, and information letter are attached for your kind verification. As the portal does not support video uploads, a walk-through video demonstrating the physical segregation of the facility has been shared via the following link: https://drive.google.com/file/d/1y-N4J20WxDmR1ZheT2DGNrl0iZhgmSvM/view?usp=sharing " Reply from manufacturer mentions that "Hereby Hebei Hope Harmony Pharmaceutical Co., Ltd. informs that our company have dedicated β-lactam workshop and specialized production line for penicillin products. Workshop 204 has been designated as a production workshop for β-lactam products. It occupies a separate building with its own water treatment system, industrial gas system, and HVAC system, along with specialized isolation and waste disposal methods. This workshop includes an injection production line, which is suitable for penicillin injection products, including Amoxyhope (Amoxicillin injection 15%). Please refer to 3rd floor (Production line layout (Injection)) in Builing#3, Workshop 204 in the attached site lay out". Firm provided following documents: Amoxyhope-Production-Line-Layout-1.pdf Amoxyhope-Production-site-layout.pdf 5.-Amoxyhope-information-letter.pdf Undertaking-letter.pdf Clarification-Documents--Amoxyhope-Amoxicillin-Injection-15.pdf	
	Decision	
	Approved	
	Approved subject to verification of dedicated manufacturing facility via virtual inspection of manufacturer abroad, by panel of inspectors constituted by the Chairman, Registration Board.	
816	Case Category	Import (Sara Mehreen)
	Name, address of Applicant.	Minaa Medicos MR 127- 128, SHOP NO. 15, KATCHI GALI NO.2, MARRIOT ROAD, Karachi South Lyari Town (0152)

Application Form Dy. No / Tracking ID & date of submission	(6JU-8SE-STD2, 2025-11-07)
Detail of Fee Submitted	313500, 2025-11-05,
The proposed proprietary name / brand name	1gm Ceftiofur injection"
Label Claim	Each vial contains.....1 gram ceftiofur (as sodium)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1-De-Controlled
Shelf Life (Unit)	3 Year(s)Store in a refrigerator (2 °C - 8°C). Protect from light.
For generic drugs (me-too Status)	Ceftisel Dry Powder Injection 1gm pak reg# 114794
Pharmacotherapeutic Group of (API)	Antibiotic
Name, address of Manufacturing site:	M/s.Hebei Hope Harmony Pharmaceutical Co.,ltd-Industry Development Area Yuanshi County,Shijiazhuang City,Hebei Province,People's Republic of China-China
Name, address of Marketing Authorization Holder:	M/s.Hebei Hope Harmony Pharmaceutical Co.,ltd, Industry Development Area Yuanshi County,Shijiazhuang City,Hebei Province,People's Republic of China, China
Details of Certificates (CoPP/FSC/cGMP):	Firm submitted copy of apostilled GMP certificate issued by Deptt. of Agriculture & Rural Affairs of Hebei Province, China.
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
Evaluation Remarks	
Case was deferred in 356th meeting of the Registration Board for verification of dedicated manufacturing facility for Penicillin. Minutes of said meeting were communicated to firm. Firm replied as following: "With reference to the observation of the Registration Board regarding verification of dedicated manufacturing facility, we hereby submit the undertaking and supporting documents provided by the manufacturer for 1gm Ceftiofur Injection (Ceftiofur Sodium Powder for Injection 1g). It is submitted that the above-mentioned product is manufactured in a dedicated Cephalosporin (β-lactam) facility, i.e., Workshop 207, with a separate powder-for-injection production line. Although the facility is located within the same building structure, it is established on a separate floor with completely independent HVAC systems, utilities, personnel flow, and material flow, ensuring full compliance with cGMP requirements and prevention of cross-contamination. Supporting documents including site layout, production layout, undertaking, and information letter are attached for your kind verification. As the portal does not support video uploads, a walk-through video demonstrating the physical segregation of the facility has been shared via the following link: https://drive.google.com/file/d/1y-N4J20WxDmR1ZheT2DGNr10iZhgmSvM/view?usp=sharing " Letter from manufacturer mentions that "Hereby Hebei Hope Harmony Pharmaceutical Co., Ltd. informs that our company have dedicated β-lactam workshop and specialized production line for penicillin products. Workshop 207 has been designated as a production workshop for β-lactam (cephalosporins) products. It occupies a separate building with its own water treatment system, industrial gas system, and HVAC system, along with specialized isolation and waste disposal methods. This workshop includes a powder for injection production line, which is suitable for cephalosporin powder for injection products, including 1gm Ceftiofur Injection (Ceftiofur sodium powder for injection 1g). Please refer to 2nd floor (Production line layout (Powder for injection)) in Building #3, Workshop 207 in the ". Firm provided following documents: Amoxyhope-Production-Line-Layout-1.pdf Amoxyhope-Production-site-layout.pdf 5.-Amoxyhope-information-letter.pdf Undertaking-letter.pdf Clarification-Documents--Amoxyhope-Amoxicillin-Injection-15.pdf	

	Decision	
	Approved	
	Approved subject to verification of dedicated manufacturing facility via virtual inspection of manufacturer abroad, by panel of inspectors constituted by the Chairman, Registration Board.	
817	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	SAMI Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi (000072)
	Application Form Dy. No / Tracking ID & date of submission	(8SP-T25-JLYR, 2024-09-23)
	Detail of Fee Submitted	75000.0, 2024-08-13,
	The proposed proprietary name / brand name	NIMS 3% Gel
	Label Claim	Each 1 g of gel contains: Nimesulide 30mg Innovator Specs.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	De-Controlled-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store over 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LIMITED, Plot No. N-198, M.I.D.C., Tarapur, Boisar, Tal. Palghar, Dist. Thane, Maharashtra, INDIA
	Detail of stability batches of drug product	Firm provided 6 months stability study data of three trial batches manufactured.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm provided Drug Import License for import of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm provided pharmaceutical equivalence.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Aulin 3% Gel, AIFA Approved
	GMP status of the firm	GMP certificate issued to firm dated 12.08.2024.
	Evidence of approval of manufacturing facility	As per letter dated 13.10. 2023 firm has cream/ ointment/ gel (General) section.
	Evaluation Remarks	
	Decision	
	Approved	
818	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Medifine Laboratories (Pvt) Ltd. Plot No A-11, New Industrial Area, Mirpur, Azad Kashmir (000672)
	Application Form Dy. No / Tracking ID & date of submission	(P8Q-97S-WWPD, 2024-03-01)
	Detail of Fee Submitted	30000.0, 2024-01-24,
	The proposed proprietary name / brand name	Isomedi 0.05% Gel
	Label Claim	Each gram of gel contains:Isotretinoin.....0.5mg (0.05%w/w)

	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10g-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C at cool and dry place
	For generic drugs (me-too Status)	Isotin 0.05%w/w Gel by M/s Shaigan Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Retinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	400 Tubes 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from M/s Seraph Pharmaceutical(E 3889586528271) 06.01.23
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Isotrex 0.05% Gel (Manufactured by M/s GSK Pakistan)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Isotrex 0.05% w/w Gel by Stiefel Laboratories (Ireland) Ltd, Finisklin Business Park, Sligo, Ireland
	GMP status of the firm	No F.3-97/2022-Add.dir (Qa-Lt-1)dated 22-August-2022 mentioning cream ointment lotion section
	Evidence of approval of manufacturing facility	No F.5-1/2025-Lic (Vol-1)dated 15-february-2021 mentioning cream ointment lotion general section
Evaluation Remarks		
"The application is complete as per codal formalities for consideration by the Registration Board"		
Decision		
Approved		
819	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Danas Pharmaceuticals (Pvt) Ltd. 312-Industrial Triangle, Kahuta road,Islamabad. (000569)
	Application Form Dy. No / Tracking ID & date of submission	(JA3-7H7-ZQTU, 2024-02-26)
	Detail of Fee Submitted	75000.0, 75000.0 2023-11-08, 2023-11-08
	The proposed proprietary name / brand name	Dancef Injection 500 mg IM
	Label Claim	Each vial contains: Ceftriaxone as Sodium.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 Year(s)Ceftriaxone for injection sterile powder should be
	For generic drugs (me-too Status)	Oxidil injection of Sami
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Evolution Pharmaceuticals (Pvt.)Ltd-Plot #: 25 & 26, Street #: S-3 RCCI, National Industrial Zone Rawat, Islamabad - Pakistan -
	Name & address of API manufacturer	SinopharmWeiqida Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	16500 vials: 3 batches

	Documents for the procurement of API with approval from DRAP (in case of Import)	03-02-2023: clearance certificate submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Oxidil Injection of Sami: PE studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	(Evolution pharma: 11-01-2023: GMP certificate
	Evidence of approval of manufacturing facility	(Evolution pharma) 10-07-2017: Issuance of DML letter specifies Dry vial injection (Cephalosporin) section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
820	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Healthtek Pvt. Ltd. Plot No.14, Sector 19, Korangi Industrial Area Karachi - Pakistan (000618)
	Application Form Dy. No / Tracking ID & date of submission	(GWL-H4A-J793, 2024-10-25)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-01, 2024-10-24
	The proposed proprietary name / brand name	2SUM 1.5g Injection IV/IM
	Label Claim	Each vial contains: Sterile Cefoperazone sodium eq. to Cefoperazone.....1000mg Sterile Sulbactam Sodium eq. to Sulbactam 500mg (Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	De-regulated-De-Controlled
	Shelf Life (Unit)	2 Year(s)Don't store over 30°C
	For generic drugs (me-too Status)	Cefpran 1.5g Injection
	Pharmacotherapeutic Group of (API)	Antibiotics (Cephalosporin)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 Batches Size 1L 130 vials
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 Computerized No: K-2889286421268 Date of issue: 11-Jan-2024
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefpran 1.5gm Injection marketed by ontech corporation B. No: 230701
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Sulperazone*
	GMP status of the firm	Certificate no 29/2025-DRAP dated 14-03-25
	Evidence of approval of manufacturing facility	No F.2-10/2003-Lic (Vol-II)dated 26-december-2024 mentioning dry powder injection section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	

	Decision	
	Approved	
821	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbelli road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(22E-9BH-W3MU, 2024-10-28)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-15, 2024-10-21
	The proposed proprietary name / brand name	Cefto 1000mg Injection
	Label Claim	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone.....1000mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25 Degree Centigrade
	For generic drugs (me-too Status)	Rocephin Injection 1000mg (Manufactured by Martin Dow Pvt. Ltd)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co. Ltd. Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi
	Detail of stability batches of drug product	3 batches commercial packs used
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-2216462404126 5.8.22
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Claforan dry injection M/s snofi
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Ceftriaxone for Injection 1000mg USP (Manufactured by Sandoz Pvt. Ltd.)
	GMP status of the firm	No F.91/2024-DRAP K dated 27-06-2024
	Evidence of approval of manufacturing facility	No F.1-38/2011-Lic (Vol-I)dated 8-june -2021 mentioning dry powder injection cephalosporin section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
822	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Orbis Pharmaceuticals Plot # K-138 , SITE Super Highway Phase 2 , Karachi (000979)
	Application Form Dy. No / Tracking ID & date of submission	(MJG-HPS-BQL6, 2025-04-16)

	Detail of Fee Submitted	37000.0, 2025-02-17,
	The proposed proprietary name / brand name	Terbi
	Label Claim	Each gram of Terbinafine HCL 1% w/w contain: Terbinafine HCL 10mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10gm,15gm and 20gm-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in cool & dry place below 30oC
	For generic drugs (me-too Status)	Tersil by Sami pharmaceuticals (RN No.37713)
	Pharmacotherapeutic Group of (API)	antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Tagoor Laboratories Pvt. limited Factory survey- 29,tupakulagudem village ochavaram panchayat tallapudi mandal west Godavari district Andhra Pradesh 534342 India
	Detail of stability batches of drug product	3 batches 200 tubes
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearnce certificate issued to M/s Shrooq is submitted. Copy of Loan letter from M/s Shrooq and copy of intimation of loan from M/s Orbis to DRAP, are submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE submitted against lamisil cream 1 %
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	iv-A
	The status in reference regulatory authorities	terbinafine HCl by Karo healthcare (USFDA Approved)
	GMP status of the firm	new dml
	Evidence of approval of manufacturing facility	F.2-11/2017-Lic issued on 27-10-2023 mentioned cream/ointment section general
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
823	Case Category	Routine (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	(X7Q-DGH-QT46, 2024-10-29)
	Detail of Fee Submitted	75000.0, 18000.0 2024-05-23, 2024-10-09
	The proposed proprietary name / brand name	Ceftramed 1000mg Injection IV
	Label Claim	Each vial contains: Ceftriaxone Sodium eq to Ceftriaxone.....1000mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25 Degree Centigrade
	For generic drugs (me-too Status)	Rocephin Injection 1000mg (Manufactured by Martin Dow Pvt. Ltd)
	Pharmacotherapeutic Group of (API)	Antibiotics

	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co. Ltd. Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi
	Detail of stability batches of drug product	3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-2216462404126 5.8.22
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Claforan dry injection M/s snofi
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Ceftriaxone for Injection 1000mg USP (Manufactured by Sandoz Pvt. Ltd.)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	No F.1-38/2011-Lic (Vol-I)dated 8-june -2021 mentioning dry powder injection cephalosporin section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
824	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Danas Pharmaceuticals (Pvt) Ltd. 312-Industrial Triangle, Kahuta road,Islamabad. (000569)
	Application Form Dy. No / Tracking ID & date of submission	(PVW-MTY-1SE3, 2024-09-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-09-02, 2024-09-26
	The proposed proprietary name / brand name	Lanzop-D
	Label Claim	Each capsule contains: Dexlansoprazole Dual Delayed release pellets eq. to Dexlansoprazole.....60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30 degree centigrade
	For generic drugs (me-too Status)	Dextol 60mg DDR Capsule (Seraph Pharma)
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor WHO ATC code: A02BC06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Vision Pharmaceuticals Pvt Ltd Islamabad
	Detail of stability batches of drug product	Three production batches having 1500 cap batch size
	Documents for the procurement of API with approval from DRAP (in case of Import)	Locally purchased M/s Vision
	Pharmaceutical Equivalence and Comparative Dissolution Profile	DEXILANT 30 mg capsules by Acino"

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Dexilant 60mg Capsule (Takeda Pharmaceuticals America, Inc USP)
	GMP status of the firm	3-103/2023-Add.dir (Qa-Lt-1-44) 10.01.23
	Evidence of approval of manufacturing facility	No F.1-44/2003-Lic dated 21-02-2023 mentioning capsule section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
825	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	gulfpharmaceuticals Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. (000750)
	Application Form Dy. No / Tracking ID & date of submission	(D69-7BE-5UMH, 2024-07-22)
	Detail of Fee Submitted	30000.0, 2024-05-27,
	The proposed proprietary name / brand name	scedex 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-De-Controlled
	Shelf Life (Unit)	2 Year(s)15°C to 25°C
	For generic drugs (me-too Status)	Dextop 60mg Searl Pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor WHO ATC code: A02BC06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceutical Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan
	Detail of stability batches of drug product	Three production batches having 5000 cap batch size
	Documents for the procurement of API with approval from DRAP (in case of Import)	Locally purchased M/s Vision
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Dextop 60mg capsules by Searle”
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Product Name: Dexilant Company: Takeda Pharmaceuticals USA, Inc. Regulatory Authority: FDA Address: Massachusetts, United States
	GMP status of the firm	3-50/2020-Add.dir (Qa-Lt-1) 07.03.24
	Evidence of approval of manufacturing facility	No F.1-37/2010-Lic dated 20-07-2020 mentioning capsule section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	

	Decision	
	Approved	
826	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	gulfpharmaceuticals Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. (000750)
	Application Form Dy. No / Tracking ID & date of submission	(S38-YAV-E3BM, 2024-07-05)
	Detail of Fee Submitted	30000.0, 2024-05-27,
	The proposed proprietary name / brand name	scedex 30mg 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-De-Controlled
	Shelf Life (Unit)	2 Year(s)15°C to 25°C
	For generic drugs (me-too Status)	Dextop 30mg Searl Pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor WHO ATC code: A02BC06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceutical Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan
	Detail of stability batches of drug product	Three production batches having 5000 cap batch size
	Documents for the procurement of API with approval from DRAP (in case of Import)	Locally purchased M/s Vision
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Dextop 60mg capsules by Searle”
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Product Name: Dexilant Company: Takeda Pharmaceuticals USA, Inc. Regulatory Authority: FDA Address: Massachusetts, United States Telephone: +1-877-825-3327
	GMP status of the firm	3-50/2020-Add.dir (Qa-Lt-1) 07.03.24
	Evidence of approval of manufacturing facility	No F.1-37/2010-Lic dated 20-07-2020 mentioning capsule section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
827	Case Category	Routine (Shahrukh Ali)
	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	(R89-Z6Z-VZ7Y, 2024-08-21)
	Detail of Fee Submitted	75000.0, 2024-08-02,
	The proposed proprietary name / brand name	Fusiderm
	Label Claim	Eachgmcontains: Fusidic Acid.....20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10g, 15g, 20g, 30g, -As per SRO
	Shelf Life (Unit)	24 Year(s)Do not store above 25°C
	For generic drugs (me-too Status)	Bacusid Cream, Sami Pharmaceuticals Pvt. Ltd., 090779
	Pharmacotherapeutic Group of (API)	Antibiotic for Topical use (ATC code: D06AX01)
	Name, address of Manufacturing site:	Genix Pharma Pvt. Ltd.-44, 45-B, Korangi Creek Road, Karachi-
	Name & address of API manufacturer	Joyang Laboratories
	Detail of stability batches of drug product	3 batches Batch Size 1000 g
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 K-2441980624283
	Pharmaceutical Equivalence and Comparative Dissolution Profile	(Fucidin H cream Leo laboratories
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Fusidic acid 20mg/g cream, Focus Pharmaceuticals Ltd., MHRA
	GMP status of the firm	Certificate no 41/2023-dRAP-k dated 23-06-23
	Evidence of approval of manufacturing facility	No F.2-12/93-Lic (vOL-v) dated 27-sep-16 mentioning cream section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
828	Case Category	Routine (Shahrukh Ali)
	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	(989-ER9-HZP5, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-07-23,
	The proposed proprietary name / brand name	Fusin
	Label Claim	Each gm contains: Fusidic Acid 20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10g, 15g, 20g, 30g, -As per SRO
	Shelf Life (Unit)	24 Year(s)Do not store above 25°C. Do not refrigerate
	For generic drugs (me-too Status)	Bacusid Cream, Sami Pharmaceuticals Pvt. Ltd., 090779
	Pharmacotherapeutic Group of (API)	Antibiotic for Topical use (ATC code: D06AX01)

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Joyang Laboratories
	Detail of stability batches of drug product	3 batches Batch Size 1000 g
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 K-2441980624283
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fusidic acid 20 mg/g cream Focus Pharmaceuticals Ltd Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Fusidic acid 20mg/g cream, Focus Pharmaceuticals Ltd., MHRA
	GMP status of the firm	Certificate no 41/2023-dRAP-k dated 23-06-23
	Evidence of approval of manufacturing facility	No F.2-12/93-Lic (vOL-v) dated 27-sep-16 mentioning cream section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
829	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Bio-Next Pharmaceuticals plot no 50 street no S-10 RCCI Rawat (000910)
	Application Form Dy. No / Tracking ID & date of submission	(JVN-W9T-RNZP, 2024-08-01)
	Detail of Fee Submitted	75000.0, 2024-05-25,
	The proposed proprietary name / brand name	Nextone 2gm Injection IM/IV
	Label Claim	Each vial Contains:
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30
	For generic drugs (me-too Status)	Tuff 2gm Injection
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd.,-Plot No. 145, Industrial triangle Kahuta road Islamabad.-
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceuticals Co Ltd,
	Detail of stability batches of drug product	8333 packs batch size 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-16283355574178 17.6.22
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Oxidil 2g injection M/s sammi
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	MHRA approved
	GMP status of the firm	

	Evidence of approval of manufacturing facility	No F.1-12/89-Lic (Vol-II)dated 27-02 -2011 mentioning dry powder injection cephalosporin section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
830	Case Category	Routine (Shahrukh Ali)
	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	(QMN-A7U-3551, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2024-02-28,
	The proposed proprietary name / brand name	Lanso 30mg Capsule
	Label Claim	Each capsule contains: Dexlansoprazole dual delayed release pellets equivalent to Dexlansoprazole 30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10, 30's and 14's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 Degree Centigrade
	For generic drugs (me-too Status)	Razodex 30mg Capsule by Getz Pharma Reg No. 086976
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals, Islamabad
	Detail of stability batches of drug product	1000 capsules 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	M/s Vision
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Razodex 30mg Capsules Manufactured by M/s Getz Pharma (Pvt.) Ltd Karachi- Pakistan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Dexilant Capsule Manufactured by Takeda Pharmaceuticals USA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	No F.1-38/2011-Lic (Vol-I)dated 8-june -2021 mentioning capsule section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
831	Case Category	Routine (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	(WLR-ESR-G8VQ, 2024-08-28)

	Detail of Fee Submitted	75000.0, 2024-06-21,
	The proposed proprietary name / brand name	dexowel 30
	Label Claim	30 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 °C
	For generic drugs (me-too Status)	razodex 30 by Getz phrma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor WHO ATC code: A02BC06
	Name, address of Manufacturing site:	M/S Winlet pharma-30 km lahore sargodha road sargodha-
	Name & address of API manufacturer	Ms surge pharma
	Detail of stability batches of drug product	Commercial batch 001 5,000 Packs
	Documents for the procurement of API with approval from DRAP (in case of Import)	Locally purchased M/s Surge
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Razodex 30mg Capsules Manufactured by M/s Getz Pharma (Pvt.) Ltd Karachi- Pakistan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/la
	GMP status of the firm	Firm has applied for cGMP certificate dated 12.02.25
	Evidence of approval of manufacturing facility	No F.1-28/2009-Lic (Vol-1)dated 26-february-2018 mentioning tablet section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
832	Case Category	Routine (Shahrukh Ali)
	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	(5BR-TLN-9R1J, 2024-08-22)
	Detail of Fee Submitted	75000.0, 2024-08-06,
	The proposed proprietary name / brand name	Fusiderm-H
	Label Claim	Each gm contains: Fusidic Acid 20mg Hydrocortisone Acetate 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10g, 15g, 20g, 30g, -As per SRO
	Shelf Life (Unit)	24 Year(s)Do not store above 30°C
	For generic drugs (me-too Status)	Melas- H, Atco Laboratories, 048512
	Pharmacotherapeutic Group of (API)	Antibiotic for Topical use (ATC code: D06AX01)
	Name, address of Manufacturing site:	Genix Pharma Pvt. Ltd.-44, 45-B, Korangi Creek Road, Karachi-
	Name & address of API manufacturer	Joyang Laboratories (Fusidic acid) Tianjin Jinjin Pharmaceutical Co., Ltd (Hydrocortisone HCl)
	Detail of stability batches of drug product	3 batches Batch Size 1000 g

	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: K-2243180625927
	Pharmaceutical Equivalence and Comparative Dissolution Profile	(Fucidin H cream Leo laboratories
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Fucidin H cream, Leo laboratories limited, UK
	GMP status of the firm	Certificate no 41/2023-dRAP-k dated 23-06-23
	Evidence of approval of manufacturing facility	No F.2-12/93-Lic (vOL-v) dated 27-sep-16 mentioning cream section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
833	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	AUSPEC PHARMACEUTICALS PVT LTD 21, Km, Raiwind Road, Lahore. (000964)
	Application Form Dy. No / Tracking ID & date of submission	(T1N-Q49-6VQM, 2024-06-03)
	Detail of Fee Submitted	75000.0, 2024-02-06,
	The proposed proprietary name / brand name	D3V Oral/I.M. Ampoule
	Label Claim	Each 1ml ampoule Contains: Cholecalciferol (Vitamin D3)....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1ml x 5's/As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 30C
	For generic drugs (me-too Status)	Sunny D Insta Ampoule by M/s Scotmann Pharmaceuticals Islamabad
	Pharmacotherapeutic Group of (API)	A11CC05
	Name, address of Manufacturing site:	Aulton Pharmaceuticals-Plot # 84/1, Block A, Phase 5, Industrial Estate, Hattar, Pakistan-
	Name & address of API manufacturer	M/s Sichuan Province Yuxin Pharmaceutical Co Ltd. by M/s Sichuan Province Yuxin Pharmaceutical Co Ltd.
	Detail of stability batches of drug product	Three batches having 25000 Ampoules
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-5 submitted alongwith GD&Invoice
	Pharmaceutical Equivalence and Comparative Dissolution Profile	DOW-D 5MG/ML INJECTION M/s Martin Dow
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	VITAMIN D3 BON 200,000 IU/1 ml solution for Injection IM ampoule by BOUCHARA RECORDATI LE WILSON BUILDING 70 AVENUE DU GENERAL DE GAULLE 92800 PUTEAUX, FRANCE

	GMP status of the firm	11-94/2021-Aulton-Drap-38 DRAP dated 27.03.25
	Evidence of approval of manufacturing facility	No. F.1-17/2013-LIC (Vol-1) dated 3 -11-2015 mentioning Liquid injection general section.
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
834	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Meditech Pharmaceuticals Plot No. 83-A,83-B, Industrial Estate, Hayatabad, Peshawar (000544)
	Application Form Dy. No / Tracking ID & date of submission	(9Z4-RV3-Z8G4, 2024-10-28)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-04, 2024-10-24
	The proposed proprietary name / brand name	Dexilon
	Label Claim	Each Capsule contains: Dual delayed release dextansoprazole Pellets eq to Dextansoprazole 60mg (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30 Capsules-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Delanzo DDR Capsules by Sami Pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor WHO ATC code: A02BC06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals, plot no 22-23,Industrial Triangle, Kahuta Road, Islamabad,Pakistan
	Detail of stability batches of drug product	Three production batches having 28 packs batch size
	Documents for the procurement of API with approval from DRAP (in case of Import)	Locally purchased M/s vision
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Delanzo 30 mg capsules by Sami"
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	FDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	No F.3-4/2021-Lic dated 24-08-2022 mentioning capsule section
	Evaluation Remarks	
	At the time of Product Development our HPLC System is not 21 CFR complaint therefore the audit trail report are not applicable.	
	Decision	
	Rejected	
	Rejected, as the firm has submitted that compliance record of HPLC software with 21 CFR and audit trail reports for product testing are not available.	
835	Case Category	Routine (Shahrukh Ali)

	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	(V63-5TH-7UPU, 2024-08-29)
	Detail of Fee Submitted	30000.0, 2024-08-06,
	The proposed proprietary name / brand name	Fusin- H
	Label Claim	Each gm contains: Fusidic Acid 20mg Hydrocortisone Acetate 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10g, 15g, 20g, 30g, -As per SRO
	Shelf Life (Unit)	24 Year(s)Do not store above 30°C
	For generic drugs (me-too Status)	Melas- H, Atco Laboratories, 048512
	Pharmacotherapeutic Group of (API)	Antibiotic for Topical use (ATC code: D06AX01)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Joyang Laboratories (Fusidic acid) Tianjin Jinjin Pharmaceutical Co., Ltd (Hydrocortisone HCl)
	Detail of stability batches of drug product	3 batches Batch Size 1000 g
	Documents for the procurement of API with approval from DRAP (in case of Import)	commercial invoice submitted only
	Pharmaceutical Equivalence and Comparative Dissolution Profile	(Fucidin H cream Leo laboratories
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Fucidin H cream, Leo laboratories limited, UK
	GMP status of the firm	Certificate no 41/2023-dRAP-k dated 23-06-23
	Evidence of approval of manufacturing facility	No F.2-12/93-Lic (vOL-v) dated 27-sep-16 mentioning cream section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
836	Case Category	Import (Shahrukh Ali)
	Name, address of Applicant.	Skymed Healthcare Private Limited House No:2, Gor-1 near Chamba House Lahore, Pakistan. (05-352-0063-038947D)
	Application Form Dy. No / Tracking ID & date of submission	(4JR-T21-8XWB, 2025-02-21)
	Detail of Fee Submitted	300000.0, 2024-12-03,
	The proposed proprietary name / brand name	Optivue Injection
	Label Claim	each injection contains Iopamidol 370mgI/ml in 50ml.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 vial per box.-As per SRO
	Shelf Life (Unit)	36 Year(s)Store below 30 degrees celsius and protect from light.

	For generic drugs (me-too Status)	- Iopamiro 370 Injection. Registration No: 015791
	Pharmacotherapeutic Group of (API)	WHO ATC code of Iopamidol: V08AB04
	Name, address of Manufacturing site:	Beijing Beilu Pharmaceutical Co., Ltd.-No. 3, Shuiyuan West Road, Miyun District, Beijing, China.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	isovue 370 m/s bracco diagnostics
	Name, address of Marketing Authorization Holder:	Beijing Beilu Pharmaceutical , No. 3, Shuiyuan West Road, Miyun District, Beijing, China., China
	Details of Certificates (CoPP/FSC/cGMP):	Copp valid till 13.01.25
	Details of Authorization Letter :	imported drug
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	zone iv-A
	The status in reference regulatory authorities	USA, Japan, Italy.
	Evaluation Remarks	
	Copp expired firm has submitted that it has applied for copp and they will provide it before issuance of registration letter	
	Decision	
	Approved	
	Approved, firm will submit valid Copp before issuance of registration letter	
837	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	The Searle Company Limited Plot No. F-319, Sindh Industrial Trading Estate (SITE) (000016)
	Application Form Dy. No / Tracking ID & date of submission	(ETM-VPG-W4J7, 2024-08-26)
	Detail of Fee Submitted	75000.0, 2024-08-09,
	The proposed proprietary name / brand name	Namic 500mg Tablet (Mefenamic acid)
	Label Claim	Each Film coated tablet contains: Mefenamic Acid..... 500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 °C.
	For generic drugs (me-too Status)	Ponstan Forte Tablet 500mg, Pfizer Pakistan Limited
	Pharmacotherapeutic Group of (API)	Analgesic
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batch Size=1800 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: E-4678282807468 Date of issue: 17-Mar-2023 Loan from M/s Jawa
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ponstan forte 500mg film coated Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Mefenamic Acid 500 mg Film-Coated Tablets, United Kingdom

	GMP status of the firm	188 /2023-DRAP the, 14.11.2023 CONTRACT ACCEPTOR
	Evidence of approval of manufacturing facility	No. F.1-51/2024-Lic dated 7 .02. 2014 mentioning Tablet (General).
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
838	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(6HR-HGQ-WNZN, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-07-24,
	The proposed proprietary name / brand name	Mefexa 500mg Tablet
	Label Claim	Each tablet contains: Mefenamic Acid..... 500mg (B.P specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, 2x10's, 2x7' -As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool & Dry place below 30
	For generic drugs (me-too Status)	Ponstan Forte Tablet 500mg of M/s Pfizer
	Pharmacotherapeutic Group of (API)	Analgesic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shaanxi Baoxin Pharmaceutical Co.,Ltd. Add: Caijiapo Economic & Technical Development Zone, Qishan County, Baoji City, Shaanxi Province, China
	Detail of stability batches of drug product	Batch Size=1800 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: E-4678282807468 Date of issue: 17-Mar-2023 Loan from M/s Jawa
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ponstan forte 500mg film coated Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Ponstan Forte 500 mg Film-coated Tablets of M/s Dales Pharmaceutical Ltd, Snaygill industrial estate, Keighley Road, skiptaon, BD23 2RW, UK. (MHRA & HPRA Approved)
	GMP status of the firm	188 /2023-DRAP the, 14.11.2023 CONTRACT ACCEPTOR
	Evidence of approval of manufacturing facility	No. F.1-51/2024-Lic dated 7 .02. 2014 mentioning Tablet (General).
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	

839	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	AsianContinental (Pvt.) Ltd. D-32, S.I.T.E II, Super Highway, Karachi (000643)
	Application Form Dy. No / Tracking ID & date of submission	(1Z1-DSV-X3Y9, 2024-09-02)
	Detail of Fee Submitted	75000.0, 2024-07-24,
	The proposed proprietary name / brand name	Mefasian 500mg Tablet
	Label Claim	Each tablet contains: Mefenamic Acid..... 500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, 2x10's, 2x7'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 °C
	For generic drugs (me-too Status)	Ponstan Forte Tablet 500mg (Pfizer pakistan limited)
	Pharmacotherapeutic Group of (API)	Analgesic
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Limited-Plot # 129, Sunder Industrial Estate Lahore-
	Name & address of API manufacturer	Shaanxi Baoxin Pharmaceutical Co.,Ltd
	Detail of stability batches of drug product	Batch Size=1800 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: E-4678282807468 Date of issue: 17-Mar-2023 Loan from M/s Jawa
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ponstan forte 500mg film coated Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Ponstan Forte 500 mg Film-coated Tablet (Dales Pharmaceutical Ltd, Snaygill industrial estate, Keighley Road, skipton, BD23 2RW, UK)
	GMP status of the firm	188 /2023-DRAP the, 14.11.2023 CONTRACT ACCEPTOR
	Evidence of approval of manufacturing facility	No. F.1-51/2024-Lic dated 7 .02. 2014 mentioning Tablet (General).
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	

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

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

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. Sample were drawn for the purpose of test/analysis on prescribed form-3.

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

3. Federal Government Analyst, Central Drugs Laboratories, Karachi declared the below mentioned batches of FAMILA 28F TABLET” manufactured by M/s 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 “ <i>Substandard</i> ” on the basis of Content Uniformity (Levonorgestrel) <i>Does not comply</i> Limit: meets the requirements Weight variation (Ferrous Iron) <i>Does not comply</i> Limit: meets the requirements	PWD-6-25-000162 dated 28 th 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 “ <i>Substandard</i> ” on the basis of Content Uniformity (Levonorgestrel) <i>Does not comply</i> Limit: meets the requirements Content Uniformity (Ethinyl estradiol) <i>Does not comply</i> Limit: meets the requirements Assay (Levonorgestrel):134.8% <i>Does not comply</i> Limit: 90.0% to 110.0%	PWD-5-25-000129 dated 17 th July, 2025
3.	Tab. Famila	M/s. Zafa	K-203	05-	05-	Sample has been declared	PWD-6-

	28F Reg. No 023941	Laboratories, A-46, SITE North Karachi		2025	2028	as “ <i>Substandard</i> ” on the basis of Weight variation (Ferrous Iron) <i>Does not comply</i> Limit: meets the requirements	25-000148 dated 17 th July, 2025,
4.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-207	05- 2025	05- 2028	Sample has been declared as “ <i>Substandard</i> ” on the basis of Weight variation (Ferrous Iron) <i>Does not comply</i> Limit: meets the requirements	PWD-6- 25-000152 dated 17 th July, 2025
5.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-184	04- 2025	04- 2028	Sample has been declared as “ <i>Substandard</i> ” on the basis of Content Uniformity (Levonorgestrel) <i>Does not comply</i> Limit: meets the requirements Content Uniformity (Ethinyl estradiol) <i>Does not comply</i> Limit: meets the requirements Assay (Levonorgestrel):144.8% <i>Does not comply</i> Limit: 90.0% to 110.0%	PWD-5- 25-000132 dated 28 th July, 2025,
6.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-190	05- 2025	05- 2028	Sample has been declared as “ <i>Substandard</i> ” on the basis of Content Uniformity (Levonorgestrel) <i>Does not comply</i> Limit: meets the requirements Content Uniformity (Ethinyl estradiol) <i>Does not comply</i> Limit: meets the requirements Assay (Levonorgestrel):26.3% <i>Does not comply</i> Limit: 90.0% to 110.0%	PWD-5- 25-000137 dated 28 th July, 2025
7.	Tab. Famila	M/s. Zafa	K-191	05-	05-	Sample has been declared	PWD-5-

	28F Reg. No 023941	Laboratories, A-46, SITE North Karachi		2025	2028	as “ <i>Substandard</i> ” 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%	25-000138 dated 28 th July, 2025
8.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-182	04- 2025	04- 2028	Sample has been declared as “ <i>Substandard</i> ” on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Weight variation (Ferrous Iron) Does not comply Limit: meets the requirements	PWD-6- 25-000146 dated 28 th July, 2025
9.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-199	05- 2025	05- 2028	Sample has been declared as “ <i>Substandard</i> ” on the basis of Content Uniformity (Ethinyl Estradiol) Does not comply Limit: meets the requirements Weight variation (Ferrous Iron) Does not comply Limit: meets the requirements	PWD-6- 25-000147 dated 28 th July, 2025
	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-204	05- 2025	05- 2028	Sample has been declared as “ <i>Substandard</i> ” on the basis of Content Uniformity (Ethinyl Estradiol) Does not comply Limit: meets the	PWD-6- 25-000149 dated 28 th July, 2025

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

						Assay (Levonorgestrel):144.0% Does not comply Limit: 90.0% to 110.0%	
14.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-187	04- 2025	04- 2028	Sample has been declared as “ Substandard ” on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Content Uniformity (Ethinyl estradiol) Does not comply Limit: meets the requirements Weight variation (Ferrous Iron) Does not comply Limit: meets the requirements Assay (Levonorgestrel):132.4% Does not comply Limit: 90.0% to 110.0% Assay (Ethinyl estradiol):126.1.0% Does not comply Limit: 90.0% to 110.0%	PWD-5- 25-000134 dated 18 th July, 2025,
15.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-192	05- 2025	05- 2028	Sample has been declared as “ Substandard ” on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Content Uniformity (Ethinyl estradiol) Does not comply Limit: meets the requirements Assay (Levonorgestrel):35.6% Does not comply Limit: 90.0% to 110.0% Assay (Ethinyl	PWD-5- 25-000139 dated 23 rd July, 2025

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

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

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

4. Federal Inspector of Drugs 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 report from FID, Lahore for following batches

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

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

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

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

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

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

“Proceedings and Decision of 313th Meeting of Registration Board.

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

- 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 ZAFSA Quality control (QC), reports these batches were found to be satisfactory and in compliance with the internal quality specifications at the time of release.

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

Technical Evaluation of OOS Investigation:

- i. Total of twenty-one (21) batches of Famila 28 Tablet were declared by CDL as sub-standard on the basis of Assay, Content Uniformity of Levonorgestrel and Ethinyl Estradiol and weight variation of Ferrous Fumarate
- ii. Multiple batches failed for content uniformity. Content uniformity issues indicate uneven distribution of active pharmaceutical ingredients (APIs).
- iii. Defect of content uniformity may not be equally distributed over the batch that's why it is not necessary for a Board or retention portion to be defective. Allowing retesting may result in false negative results and pose the risk to patient which can be avoided otherwise.
- iv. Assay values for Levonorgestrel and Ethinyl Estradiol in certain batches were far outside the permissible limit (90–110%), e.g.:

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

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

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

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

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

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

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

The Board after considering reports of CDL, Karachi showing huge difference in results of content uniformity, weight variation & assay and after thorough deliberations decided as under:
“Product Specific Inspection by panel of inspectors/experts to be nominated by Director QA/LT. After submission of the panel inspection report, the Board 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 August, 2025 in compliance to letter No. 03-02/206-QALT(353-RB) dated 12th February, 2025.

- 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**

Representative 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.*



Drug Regulatory Authority of Pakistan

(Biological Evaluation & Research Division)



Item No. IV Division of Biological Evaluation & Research

Sr. No	Title	Description
1	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Martin Dow Marker Limited Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S, Razi Road, Shahr-e-Faisal, Karachi (0523)
	Application Form Dy. No / Tracking ID & date of submission	(GY7-2AR-2J5W, 2026-02-17)
	Detail of Fee Submitted	313500, 2026-01-12,
	The proposed proprietary name / brand name	Albigen Injection 10g/vial (Human Albumin 20%)
	Label Claim	Each vial of 50 ml contains 10 g of human plasma protein of which at least 96% is Human Albumin.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per DPC/SRO-As per SRO
	Shelf Life (Unit)	36 Month(s)Store Below 30°C. Protect from light
	For generic drugs (me-too Status)	Alburx 20 by M/s Hakimsons Impex (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Blood substitutes and plasma protein fractions WHO ATC: B05AA01
	Name, address of Manufacturing site:	Grand Shuyang Life Sciences (Chengdu) Co., Ltd.-No. 888, 5th Antai Road, Hi-Tech Zone, Chengdu, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	Grand Shuyang Life Sciences (Chengdu) Co., Ltd., No. 888, 5th Antai Road, Hi-Tech Zone, Chengdu, China, China
	Details of Certificates (CoPP/FSC/cGMP):	Apostile COPP No. Sichuan20250110 dated 10-04-2025 issued by Sichuan Medical Products Administration No. 98, Yu Sha Road, Chengdu, Sichuan Province, P. R. China valid till 09-04-2027.
	Details of Authorization Letter :	LETTER OF AUTHORIZATION dated 17-10-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The bulk of Human Albumin was stored at 10~15°C for 0 hour,24 hours and 28 hours. The shelf life of the bulk of Human Albumin shall not exceed 24 hours under the storage condition of 10~15°C.
	The status in reference regulatory authorities	Human Albumin Biotest 20%, solution for infusion (UK MHRA)
Evaluation Remarks		

Manufacturer has not performed non-clinical and clinical studies on applied product and submitted following justification; Module 4: Manufacturer has submitted following justification for not performing toxicology studies; “Our company's Human Albumin has been on the market for over 38 years. The active component of this product is Human Albumin, which is derived from normal human blood. This Product is well established in the market, and their pharmacological and toxicological effects are clear. The safety of the formulation excipients has been verified over a long period, and the clinical efficacy and safety of the product have been widely recognized globally. Our company's stability test results and feedback from clinical use also sufficiently demonstrate that the product is effective, highly safe, and has few adverse reactions. Therefore, based on the above reasons, our company's non-clinical studies have primarily completed tests for hemolysis and vascular irritancy (local tolerance).” Module 5: Manufacturer has submitted following justification for not performing clinical studies; “At the time of initial registration, due to the confirmed indications and efficacy of Human Albumin, 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 Human Albumin product. In accordance with Article 10(a)(ii) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, an applicant is not required to provide the results of pre-clinical tests and clinical trials if it can be demonstrated that the active substance(s) of the medicinal product have a well-established medicinal use, with recognized efficacy and an acceptable level of safety, supported by a detailed scientific bibliography. Since the first registration of our Human Albumin, the product has been 1 manufactured and marketed for more than 38 years and remains in high demand, with a current annual sales volume of approximately 4 million vials (equivalent to 10 g/vial). Long-term stability data have consistently demonstrated stable product quality, and extensive clinical use over the years has confirmed its proven efficacy, high safety profile, and a low incidence of adverse reactions.”

Decision

Deferred

Registration decided to defer the case and advised the BE&R Division to develop criteria, in line with reference guidelines, for the clinical and non-clinical data requirements of human plasma-derived products that have been marketed in their country of origin for many years and have well-established medicinal use.

2	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006-118530D)
	Application Form Dy. No / Tracking ID & date of submission	(MUB-RTU-21WW, 2025-02-13)
	Detail of Fee Submitted	300000.0, 2025-01-15,
	The proposed proprietary name / brand name	OSTEOPARIN
	Label Claim	Each ml contains: Recombinant Human Parathyroid Hormone (1-34) USP 250 mcg, Succinic acid USP 0.29 mg, Sodium Hydroxide USP 0.05mg, Glycerol USP 50mg, M-Cresol USP 3mg, Water for Injection USP q.s
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	3ml (Osteoparin is s-As per SRO
	Shelf Life (Unit)	24 Month(s)Store at 2-8°C, protecting from light. This injection is not to be frozen.
	For generic drugs (me-too Status)	FORTEO 20mcg/80mcl of M/a Eli Lilly Karachi (Reg#043009)
	Pharmacotherapeutic Group of (API)	Parathyroid hormone analogue
	Name, address of Manufacturing site:	Virchow Biotech Pvt Ltd-Sy No 172 part, Gagillapur (V), Dundigal-Gandimaisamma (M),

		Medchal-Malkajgiri (D), Telangana, 500043-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	Virchow Healthcare Pvt. Ltd. , Sy No 172 part, Gagillapur (V), Dundigal-Gandimaisamma (M), Medchal-Malkajgiri (D), Telangana, 500043, India
	Details of Certificates (CoPP/FSC/cGMP):	COPP No of Certificate : 4309348/TS/2024 Valid UpTo : 20/05/2027 COPP is not legalized
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 1st batch is till 36months. 2nd batch is till 24 months and 3rd batch is till 12 months. Batch sizes are 25.8±3gm. Manufacturer informed that the API is manufactured for captive consumption not for commercial.
	The status in reference regulatory authorities	Forteo approved in Health Canada.
	Evaluation Remarks	
	Decision of 353rd meeting: DeferredRegistration Board decided to issue show cause notice to M/s Revive Health care, Lahore for termination of their authorization by Product License Holder i.e. M/s Virchow Biotech Private Limited, India regarding OSTEOTIDE INJECTION 750 mcg/3mL deferred in 351st meeting of Registration Board. Remarks: A show cause notice was issued to the firm M/s Revive Health Care Lahore on 24-02-2026. The firm has requested for personal hearing on 17-04-2026 and personal hearing letter was issued on 18-04-2026. It is moreover stated that the innovator product Forteo 750 mcg/3 mL was previously available in Health Canada but has been discontinued there as of February 2026. It had already been discontinued earlier by the US FDA. So, the applied strength is no longer available in any reference regulatory authority designated by Registration Board.	
	Decision	
	Rejected	
	Registration Board rejected the application due to non-availability of evidence of applied strength i.e 750mcg/3ml Pre-filled Pen/cartridge in any of the reference regulatory authorities as approved by Registration Board.	
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	(1M4-W7B-37MY, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-12,
	The proposed proprietary name / brand name	Protamin Injection
	Label Claim	Each vial contains Protamine Sulfate.... 50mg/5mL Product Specs: USP Specifications
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 MonthStore at 20°C to 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	BIOCHEM CORPORATION TAMAGAWA PLANT 2146-3 Tamagawa, Tokigawa-Machi, Hiki-gun, Saitama, 355-0342, Japan
	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	Protamine sulfate 50mg/5mL Injection (Fresenius Kabi) : FDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm currently holds approval of Biotech section only. However the applied product is naturally derived biological product. Upon inquiry, the firm stated that; "We will manufacture this product in Biotech Section as Protamine sulfate is classified by the FDA as a Human Prescription Drug (specifically under Abbreviated New Drug Application - ANDA). Biologically and chemically, it is a low molecular weight, cationic protein (peptide) It acts as a heparin antagonist and anticoagulant reversal agent."	
	Decision	
	Rejected	
	Registration Board decided to reject the application for registration of "Protamine Injection" as the applicant does not possess approval for the requisite manufacturing facility/section (non-rDNA Biological Section) issued by the Licensing Division, DRAP.	
4	Case Category	New Section (Anam Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(HBL-2VX-UYXY, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	Terza 2.5mg/0.5ml Single Dose Prefilled Syringe
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....2.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 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	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	

	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 firm was asked for Document/evidence for procurement of API i.e. DRAP attested invoice. In response, the firm submitted an invoice (not DRAP attested) and goods declaration for 300 g of tirzepatide. However, it is noted that multiple strengths of tirzepatide in both single-dose and multi-dose pen presentations have already been approved previously. Therefore, the imported quantity appears insufficient to cover the applied products, and the firm is required to provide a detailed justification supported by appropriate calculations. In the submitted stability data, phenol content has been determined; however, the applied product is a single-dose prefilled syringe, and phenol is not included in the formulation. Furthermore, impurity testing in the stability studies has been conducted only at the 9-month interval. However, the HPLC audit trail does not cover the 9-month testing interval and requires clarification. Additionally, the HPLC audit trail indicates “created manual results,” which require clarification.	
	Decision	
	Deferred	
	The Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division.	
5	Case Category	New Section (Anam Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(L6Q-MA9-PDEV, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	Terza 5mg/0.5ml Single Dose Prefilled Syringe
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....5mg (Product complies Innovator’s Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 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	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	
	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 firm was asked for Document/evidence for procurement of API i.e. DRAP attested invoice. In response, the firm submitted an invoice (not DRAP attested) and goods declaration for 300 g of tirzepatide. However, it is noted that multiple strengths of tirzepatide in both single-dose and multi-dose pen presentations have already been approved previously. Therefore, the imported quantity appears insufficient to cover the applied products, and the firm is required to provide a detailed justification supported by appropriate calculations. In the submitted stability data, phenol content has been determined; however, the applied product is a single-dose prefilled syringe, and phenol is not included in the formulation. Furthermore, impurity testing in the stability studies has been conducted only at the 9-month interval. However, the HPLC audit trail does not cover the 9-month testing interval and requires clarification. Additionally, the HPLC audit trail indicates “created manual results,” which require clarification.	
	Decision	
	Deferred	
	The Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division.	
6	Case Category	New Section (Anam Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(RY3-AGH-YSNW, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	Terza 15mg/0.5ml Single Dose Prefilled Syringe
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....15mg (Product complies Innovator’s Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 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	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	
	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 firm was asked for Document/evidence for procurement of API i.e. DRAP attested invoice. In response, the firm submitted an invoice (not DRAP attested) and goods declaration for 300 g of tirzepatide. However, it is noted that multiple strengths of tirzepatide in both single-dose and multi-dose pen presentations have already been approved previously. Therefore, the imported quantity appears insufficient to cover the applied products, and the firm is required to provide a detailed justification supported by appropriate calculations. In the submitted stability data, phenol content has been determined; however, the applied product is a single-dose prefilled syringe, and phenol is not included in the formulation. Furthermore, impurity testing in the stability studies has been conducted only at the 9-month interval. However, the HPLC audit trail does not cover the 9-month testing interval and requires clarification. Additionally, the HPLC audit trail indicates “created manual results,” which require clarification.	
	Decision	
	Deferred	
	The Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division.	
7	Case Category	New Section (Anam Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(T7X-NX2-74DW, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	Terza 10mg/0.5ml Single Dose Prefilled Syringe
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....10mg (Product complies Innovator’s Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 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	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	
	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 firm was asked for Document/evidence for procurement of API i.e. DRAP attested invoice. In response, the firm submitted an invoice (not DRAP attested) and goods declaration for 300 g of tirzepatide. However, it is noted that multiple strengths of tirzepatide in both single-dose and multi-dose pen presentations have already been approved previously. Therefore, the imported quantity appears insufficient to cover the applied products, and the firm is required to provide a detailed justification supported by appropriate calculations. In the submitted stability data, phenol content has been determined; however, the applied product is a single-dose prefilled syringe, and phenol is not included in the formulation. Furthermore, impurity testing in the stability studies has been conducted only at the 9-month interval. However, the HPLC audit trail does not cover the 9-month testing interval and requires clarification. Additionally, the HPLC audit trail indicates “created manual results,” which require clarification.	
	Decision	
	Deferred	
	The Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division.	
	Case Category	New Section (Anam Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(VLY-WU1-7VJV, 2025-12-02)
8	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	Terza 12.5mg/0.5ml Single Dose Prefilled Syringe
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....12.5mg (Product complies Innovator’s Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 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	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	
	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 firm was asked for Document/evidence for procurement of API i.e. DRAP attested invoice. In response, the firm submitted an invoice (not DRAP attested) and goods declaration for 300 g of tirzepatide. However, it is noted that multiple strengths of tirzepatide in both single-dose and multi-dose pen presentations have already been approved previously. Therefore, the imported quantity appears insufficient to cover the applied products, and the firm is required to provide a detailed justification supported by appropriate calculations. In the submitted stability data, phenol content has been determined; however, the applied product is a single-dose prefilled syringe, and phenol is not included in the formulation. Furthermore, impurity testing in the stability studies has been conducted only at the 9-month interval. However, the HPLC audit trail does not cover the 9-month testing interval and requires clarification. Additionally, the HPLC audit trail indicates “created manual results,” which require clarification.	
	Decision	
	Deferred	
	The Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division.	
9	Case Category	New Section (Anam Saeed)
	Name, address of Applicant.	Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644)
	Application Form Dy. No / Tracking ID & date of submission	(YRD-ZU9-T5YG, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	Terza 7.5mg/0.5ml Single Dose Prefilled Syringe
	Label Claim	Each PRE-FILLED SYRINGE (0.5mL) Contains: Tirzepatide.....7.5mg (Product complies Innovator’s Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 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	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	
	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 firm was asked for Document/evidence for procurement of API i.e. DRAP attested invoice. In response, the firm submitted an invoice (not DRAP attested) and goods declaration for 300 g of	

tirzepatide. However, it is noted that multiple strengths of tirzepatide in both single-dose and multi-dose pen presentations have already been approved previously. Therefore, the imported quantity appears insufficient to cover the applied products, and the firm is required to provide a detailed justification supported by appropriate calculations. In the submitted stability data, phenol content has been determined; however, the applied product is a single-dose prefilled syringe, and phenol is not included in the formulation. Furthermore, impurity testing in the stability studies has been conducted only at the 9-month interval. However, the HPLC audit trail does not cover the 9-month testing interval and requires clarification. Additionally, the HPLC audit trail indicates “created manual results,” which require clarification.

Decision

Deferred

The Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division.

10	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Hoffmann Human Health Pakistan Ltd. 1ST 32-BABAR BLOCK NEW GARDEN TOWN LAHORE (05-352-0065-013785D)
	Application Form Dy. No / Tracking ID & date of submission	(SRT-T7L-6S1G, 2025-12-24)
	Detail of Fee Submitted	313500, 2025-08-13,
	The proposed proprietary name / brand name	Human Albumin Injection 10g (20% 50ml)
	Label Claim	Each bottle contains: 10g of protein, the protein content is 20%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	36 Month(s)Store Below 30°C
	For generic drugs (me-too Status)	Albumin 20% (Buyer Pakistan)
	Pharmacotherapeutic Group of (API)	Blood substitutes and plasma protein fractions WHO ATC: B05AA01
	Name, address of Manufacturing site:	Nanyue Biopharming Corporation Ltd.-No. 28, Baisha Industrial Avenue, Baishazhou Industrial Park, Yanfeng District, Hengyang City, Hunan Province-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	Nanyue Biopharming Corporation Ltd., No. 28, Baisha Industrial Avenue, Baishazhou Industrial Park, Yanfeng District, Hengyang City, Hunan Province, China
	Details of Certificates (CoPP/FSC/cGMP):	Apostile COPP No. Human20240010 valid till 10-05-2026.
	Details of Authorization Letter :	LOA dated 18-09-2025
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	-
	The status in reference regulatory authorities	USFDA (ALBURX, ALBUMINEX, ALBUTEIN)

Evaluation Remarks

Manufacturer has performed stability studies on drug product under Zone II conditions i.e 25±2°C. Upon inquiry the manufacturer stated that "If necessary, additional long-term stability studies under 30°C will be conducted." Non-clinical and clinical studies are not performed on applied product and manufacturer has given justification as under; "The product we submitted is Human Albumin, which

	belongs to the category of nonspecific plasma protein product. This type of product has a long history of clinical use with well-established safety profiles. In accordance with the relevant regulations of China, it is exempt from clinical trials and preclinical safety studies." "The reason our company's product has not undergone clinical trials is that the China National Medical Products Administration considers the product to have high safety, a long history on the market, and has approved that clinical trials are not required for this product."	
	Decision	
	Deferred	
	Registration decided to defer the case for submission of stability data under Zone IV conditions and advised the BE&R Division to develop criteria, in line with reference guidelines, for the clinical and non-clinical data requirements of human plasma-derived products that have been marketed in their country of origin for many years and have well-established medicinal use.	
11	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Vety Care (Pvt) Ltd. Plot # 77, Street 06, I-10/3 (DHO-ISB-2760)
	Application Form Dy. No / Tracking ID & date of submission	(A4M-52P-W6B5, 2025-07-09)
	Detail of Fee Submitted	300000.0, 2025-07-07,
	The proposed proprietary name / brand name	Nobilis Gumboro D78
	Label Claim	Each dose contains: Live Avian Infectious Bursal Disease virus, strain D78.....at least 4.0 log ₁₀ TCID ₅₀
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	10000ds-De-Controlled
	Shelf Life (Unit)	2 Year(s)2-8 C
	For generic drugs (me-too Status)	Nobilis Gumboro D78 (004553)
	Pharmacotherapeutic Group of (API)	Live Viral Veterinary Vaccine
	Name, address of Manufacturing site:	Batch Release & Export: M/s Intervet International-Wim de Korverstraat, 5831 AN Boxmeer-Netherlands Production: M/s Merck Sharp & Dohme Animal Health,-Poligono Industrial EL Montalvo I, S.Zeppelin 6, Parcela 38, 37008 Carbajosa de la Sagrada, Salamanca Spain-Spain
	Name, address of Marketing Authorization Holder:	Intervet Nederland B.V., Wim de Korverstraat 35, 5831 AN Boxmeer, Netherlands
	Details of Certificates (CoPP/FSC/cGMP):	Valid legalized CoPP No. 260703 dated 13-01-2024 has been submitted.
	Details of Authorization Letter :	Copy of legalized LOA of December 2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	Product is already registered in different pack size.	
	Decision	
	Approved	
	Keeping in view the CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
12	Case Category	Routine (M. Zubair Masood)

	Name, address of Applicant.	Vety Care (Pvt) Ltd. Plot # 77, Street 06, I-10/3 (DHO-ISB-2760)
	Application Form Dy. No / Tracking ID & date of submission	(E18-TXZ-86SG, 2025-07-09)
	Detail of Fee Submitted	300000.0, 2025-07-07,
	The proposed proprietary name / brand name	Nobilis Gumboro 228E
	Label Claim	Each dose contains: Live Avian Infectious Bursal Disease virus.....at least 2.0 log ₁₀ EID ₅₀
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	10000ds-De-Controlled
	Shelf Life (Unit)	24 Month(s)2-8 C
	For generic drugs (me-too Status)	Gumboro 228E (016257)
	Pharmacotherapeutic Group of (API)	Live Viral Veterinary Vaccine
	Name, address of Manufacturing site:	Intervet International B.V.-Wim de Korverstraat, 5831 AN Boxmeer-Netherlands ,Merck Sharp and Dohme Animal Health, S.L.- Poligono Industrial EL Montalvo I, S.Zeppelin 6, Parcela 38, 37008 Carbajosa de la Sagrada, Salamanca Spain-Spain
	Name, address of Marketing Authorization Holder:	Intervet Nederland B.V., Wim de Korverstraat 35, 5831 AN Boxmeer, Netherlands
	Details of Certificates (CoPP/FSC/cGMP):	Copy of Legalized CoPP No. 260704 dated 16-01-2024.
	Details of Authorization Letter :	Copy of legalized LOA dated December, 2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	.
	Evaluation Remarks	
	Product is already registered in pack size of 1000, 2500 & 5000 Doses.	
	Decision	
	Approved	
	Keeping in view the CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
13	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Vety Care (Pvt) Ltd. Plot # 77, Street 06, I-10/3 (DHO-ISB-2760)
	Application Form Dy. No / Tracking ID & date of submission	(H35-ZRP-4AWE, 2025-07-09)
	Detail of Fee Submitted	300000.0, 2025-07-07,
	The proposed proprietary name / brand name	Nobilis ND Clone 30
	Label Claim	Each dose contains: Live Newcastle Disease virus, strain Clone 30.....at least 6.0 log ₁₀ ELD ₅₀
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	10000ds-De-Controlled
	Shelf Life (Unit)	24 Year(s)2-8 C
	For generic drugs (me-too Status)	Nobilis ND Clone 30 (044971)
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine

	Name, address of Manufacturing site:	Batch Release & Export: M/s Intervet International-Wim de Korverstraat, 5831 AN Boxmeer-Netherlands Production: M/s Merck Sharp & Dohme Animal Health,-Poligono Industrial EL Montalvo I, S.Zeppelin 6, Parcela 38, 37008 Carbajosa de la Sagrada, Salamanca Spain-Spain
	Name, address of Marketing Authorization Holder:	Intervet Nederland B.V., Wim de Korverstraat 35, 5831 AN Boxmeer, Netherlands
	Details of Certificates (CoPP/FSC/cGMP):	Copy of Legalized CoPP No. 260708 dated 09-02-2024.
	Details of Authorization Letter :	Copy of legalized LOA dated December, 2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	Product is already registered in pack size of 1000, 2500 & 5000 Doses.	
	Decision	
	Approved	
	Keeping in view the CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
14	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Vety Care (Pvt) Ltd. Plot # 77, Street 06, I-10/3 (DHO-ISB-2760)
	Application Form Dy. No / Tracking ID & date of submission	(HBX-TRW-ZSDL, 2025-07-09)
	Detail of Fee Submitted	300000.0, 2025-07-07,
	The proposed proprietary name / brand name	Nobilis IB 4-91
	Label Claim	Each dose contains: Live Avian Infectious Bronchitis virus, strain 4-91.....at least 3.6 log ₁₀ EID ₅₀
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	10000ds-De-Controlled
	Shelf Life (Unit)	24 Year(s)2-8 C
	For generic drugs (me-too Status)	Nobilis IB 4-91 (021405)
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Batch Release & Export: M/s Intervet International-Wim de Korverstraat, 5831 AN Boxmeer-Netherlands Production: M/s Merck Sharp & Dohme Animal Health,-Poligono Industrial EL Montalvo I, S.Zeppelin 6, Parcela 38, 37008 Carbajosa de la Sagrada, Salamanca Spain-Spain
	Name, address of Marketing Authorization Holder:	Intervet Nederland B.V., Wim de Korverstraat 35, 5831 AN Boxmeer, Netherlands
	Details of Certificates (CoPP/FSC/cGMP):	Copy of Legalized CoPP No. 260705 dated 16-01-2024.
	Details of Authorization Letter :	Copy of legalized LOA dated December, 2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	

	Product is already registered in pack size of 1000, 2500 & 5000 Doses.	
	Decision	
	Approved	
	Keeping in view the CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
15	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Medhouse Pharmaceuticals (PVT) Ltd. Mouza Mangowal Gharbi, 1 km off Chahmughlan Road, Tehsil & District Gujrat (09-342-0139-127900D)
	Application Form Dy. No / Tracking ID & date of submission	(GYV-7A2-W5N4, 2026-01-14)
	Detail of Fee Submitted	313500, 2026-01-02,
	The proposed proprietary name / brand name	HUI VAC COMBINO ND+IB Combined Newcastle Disease and Infectious Bronchitis Vaccine, Live (Strain La Sota+Strain H120)
	Label Claim	Each dose contains: Newcastle disease virus, strain La Sota (CVCC AV1615).....10 ^{6.0} EID ₅₀ Infectious Bronchitis virus, strain H120 (CVCC AV1514).....10 ^{3.5} EID ₅₀
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2000 doses-De-Controlled
	Shelf Life (Unit)	18 Year(s)Store at or below 02 - 08 C Temperature in dry place.
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Luoyang Huizhong Biotech Co.,Ltd-No. 25, Yuwenkai Street, Luolong District, Luoyang City, Henan Province-China
	Name, address of Marketing Authorization Holder:	Luoyang Huizhong Biotech Co.,Ltd, No. 25, Yuwenkai Street, Luolong District, Luoyang City, Henan Province, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille GMP No. (2022) GMP 16015 dated 31-03-2022 valid till 30-03-2027. Scanned Apostille FSC dated 20-01-2026 valid till 02-12-2026.
	Details of Authorization Letter :	Scanned Apostille LOA dated 26-01-2026.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	The firm has not submitted Safety and Efficacy data of field trials and submitted two documents with the following conclusion: 1. "Considering the endemic nature of ND in Pakistan, the predominance of genotype VII strains that does not match with already available traditional vaccine which are outdated and does not match with already available traditional vaccine which are outdated and does not match with genotype VII strains which are circulating in Pakistan and the availability of a structured local surveillance and vaccine adaptation mechanism, the registration of these vaccines is scientifically justified and strategically beneficial for the poultry sector of Pakistan" 2. "Since the vaccine was registered in China based on the national unified regulations (not	

independent clinical trial data of the company), and its long-term use record has verified its safety and efficacy, Chinese companies usually do not need to submit clinical data repeatedly."

Decision

Rejected

Registration Board rejected the application due to non availability of safety and efficacy data of the product.

16	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Medhouse Pharmaceuticals (PVT) Ltd. Mouza Mangowal Gharbi, 1 km off Chahmughlan Road, Tehsil & District Gujrat (09-342-0139-127900D)
	Application Form Dy. No / Tracking ID & date of submission	(J97-T5Z-STLD, 2026-01-21)
	Detail of Fee Submitted	313500, 2026-01-19,
	The proposed proprietary name / brand name	HUIVAC La Sota Strain Newcastle Disease Vaccine, Live (Strain La Sota)
	Label Claim	Each dose contains: Newcastle disease virus, strain La Sota (CVCCAV1615).....10 ^{6.0} EID ₅₀
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2000 doses-De-Controlled
	Shelf Life (Unit)	18 Year(s)Store at or below 02 - 08 C Temperature in dry place.
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Luoyang Huizhong Biotech Co.,Ltd-Address of manufacturer: No. 25, Yuwenkai Street, Luolong District, Luoyang City, Henan Province, China-China
	Name, address of Marketing Authorization Holder:	Medhouse Pharmaceuticals (Pvt.) Ltd., Plot No. 1, 1 Km off Medhouse Road, 16 Km Sargodha Road, Mangowal West, Distt Gujrat, Punjab–Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille GMP No. (2022) GMP 16015 dated 31-03-2022 valid till 30-03-2027. Scanned Apostille FSC dated 20-01-2026 valid till 02-12-2026.
	Details of Authorization Letter :	Scanned Apostille LOA dated 26-01-2026.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
Evaluation Remarks		
The firm has not submitted Safety and Efficacy data of field trials and submitted two documents with the following conclusion: 1. "Considering the endemic nature of ND in Pakistan, the predominance of genotype VII strains that does not match with already available traditional vaccine which are outdated and does not match with already available traditional vaccine which are outdated and does not match with genotype VII strains which are circulating in Pakistan and the availability of a structured local surveillance and vaccine adaptation mechanism, the registration of these vaccines is scientifically justified and strategically beneficial for the poultry sector of Pakistan" 2. "Since the vaccine was registered in China based on the national unified regulations (not independent clinical trial data of the company), and its long-term use record has verified its safety and efficacy, Chinese companies usually do not need to submit clinical data repeatedly."		

	Decision	
	Rejected	
	Registration Board rejected the application due to non availability of safety and efficacy data of the product.	
17	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Medhouse Pharmaceuticals (PVT) Ltd. Mouza Mangowal Gharbi, 1 km off Chahmughlan Road, Tehsil & District Gujrat (09-342-0139-127900D)
	Application Form Dy. No / Tracking ID & date of submission	(7ZH-418-E28S, 2026-02-03)
	Detail of Fee Submitted	313500, 2026-02-02,
	The proposed proprietary name / brand name	Huivac Clone 30 Strain Newcastle Disease Vaccine, Live (Strain Clone30)
	Label Claim	Each dose contains: Newcastle disease virus, strain Clone 30.....10 ^{6.0} EID ₅₀
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	2000 doses-De-Controlled
	Shelf Life (Unit)	18 Year(s)Store at or below 02 - 08 C Temperature in dry place.
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Luoyang Huizhong Biotech Co.,Ltd-Address of manufacturer: No. 25, Yuwenkai Street, Luolong District, Luoyang City, Henan Province, China-China
	Name, address of Marketing Authorization Holder:	Medhouse Pharmaceuticals (Pvt.) Ltd., Plot No. 1, 1 Km off Medhouse Road, 16 Km Sargodha Road, Mangowal West, Distt Gujrat, Punjab–Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille GMP No. (2022) GMP 16015 dated 31-03-2022 valid till 30-03-2027. Scanned Apostille FSC dated 20-01-2026 valid till 02-12-2026.
	Details of Authorization Letter :	Scanned Apostille LOA dated 26-01-2026.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	The firm has not submitted Safety and Efficacy data of field trials and submitted two documents with the following conclusion: 1. "Considering the endemic nature of ND in Pakistan, the predominance of genotype VII strains that does not match with already available traditional vaccine which are outdated and does not match with already available traditional vaccine which are outdated and does not match with genotype VII strains which are circulating in Pakistan and the availability of a structured local surveillance and vaccine adaptation mechanism, the registration of these vaccines is scientifically justified and strategically beneficial for the poultry sector of Pakistan" 2. "Since the vaccine was registered in China based on the national unified regulations (not independent clinical trial data of the company), and its long-term use record has verified its safety and efficacy, Chinese companies usually do not need to submit clinical data repeatedly."	
	Decision	

	Rejected	
	Registration Board rejected the application due to non availability of safety and efficacy data of the product.	
18	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Mustafa Brothers 186-D, Peoples Colony No. 1, Faisalabad (06-331-0168-031770D)
	Application Form Dy. No / Tracking ID & date of submission	(GRP-SE8-WGJJ, 2026-01-20)
	Detail of Fee Submitted	313500, 2026-01-19,
	The proposed proprietary name / brand name	ARRIAH FMD MONO "Foot and Mouth Disease Vaccine Sorbed Monovalent Serotype SAT-1, Liquid Inactivated with Gel of Aluminum Hydroxide and Saponin
	Label Claim	Each 2 ml dose contains: not less than 6PD50 for serotype SAT-1
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	18 Month2c-8C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Federal Governmental Budgetary Institution "Federa-600901 Yur'evets, Vladimir-Russia
	Name, address of Marketing Authorization Holder:	Federal Governmental Budgetary Institution "Federa, 600901 Yur'evets, Vladimir, Russia
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	The product is containing Sat-1 serotype of Foot and Mouth Disease virus. The matter of requirement of SAT-1 containing vaccine was referred to Ministry of National Food Security and following response was received from them: "The Disease Alert issued by this Ministry explicitly indicated that Pakistan is endemic with FMD A, O and Asia-1 serotypes whereas FMD SAT-1, SAT-2 and SAT-3 serotypes are not present and the country is officially free from these serotypes (Annex-I). A meeting of the Provincial Livestock Departments and a range of stakeholders including DCFA was convened under the chair of Animal Husbandry Commissioner on 22nd January 2026 to discuss the preparedness of the Provincial Livestock Departments and to deliberate on the need for vaccines. The minutes of the meeting along with the decisions taken are hyperlinked as Annex-II. Expert consensus during the meeting clearly concluded that prophylactic vaccination against FMDV SAT-1 is not required at this stage, as there is no laboratory-confirmed incursion of SAT-1 in Pakistan and uncertainty exists regarding the circulating topotypes in the region as it is challenging to determine which subtype (topotype I or topotype III) of SAT-1 may be introduced into the country. The meeting highlighted that import of SAT-1 vaccines carries inherent risks, including potential introduction of new virus strains, complications in disease surveillance due to vaccine-induced antibodies, and adverse implications for Pakistan's international trade and export certification. It was emphasized that WOAHA guidelines do not support routine vaccination against a serotype not currently circulating in the country and that vaccination decisions must be preceded by a formal risk assessment and antigenic matching with the circulating strain. The participants agreed that priority should be given to strengthening surveillance, diagnostics, and early detection, including procurement of SAT-1 diagnostic kits and confirmation of any suspected cases through the National Veterinary Laboratory. However, the meeting allowed that limited import of monovalent FMDV SAT-1 vaccine may be considered only for emergency outbreak response, under strict control of	

competent veterinary authorities (On the request of Provincial Livestock Departments) and not for commercial or general use." Registration Board in its 354th meeting on the basis of above recommendation decided the following for another SAT-1 containing vaccine: "Keeping in view the following recommendations of meeting of Provincial Livestock Departments and a range of stakeholders including DCFA convened under the chair of Animal Husbandry Commissioner on 22nd January 2026; Registration Board rejected the application: 1. Prophylactic vaccination against FMDV SAT-1 is not required at this stage, as there is no laboratory-confirmed incursion of SAT-1 in Pakistan and uncertainty exists regarding the circulating topotypes in the region as it is challenging to determine which subtype (topotype I or topotype III) of SAT-1 may be introduced into the country. 2. Import of SAT-1 vaccines carries inherent risks, including potential introduction of new virus strains, complications in disease surveillance due to vaccine-induced antibodies, and adverse implications for Pakistan's international trade and export certification. 3. WOA guidelines do not support routine vaccination against a serotype not currently circulating in the country and that vaccination decisions must be preceded by a formal risk assessment and antigenic matching with the circulating strain."

Decision

Rejected

Keeping in view the following recommendations of meeting of Provincial Livestock Departments and a range of stakeholders including DCFA convened under the chair of Animal Husbandry Commissioner on 22nd January 2026; Registration Board rejected the application:

1. Prophylactic vaccination against FMDV SAT-1 is not required at this stage, as there is no laboratory-confirmed incursion of SAT-1 in Pakistan and uncertainty exists regarding the circulating topotypes in the region as it is challenging to determine which subtype (topotype I or topotype III) of SAT-1 may be introduced into the country.
2. Import of SAT-1 vaccines carries inherent risks, including potential introduction of new virus strains, complications in disease surveillance due to vaccine-induced antibodies, and adverse implications for Pakistan's international trade and export certification.
3. WOA guidelines do not support routine vaccination against a serotype not currently circulating in the country and that vaccination decisions must be preceded by a formal risk assessment and antigenic matching with the circulating strain.

19	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	CLOUD AGRI PAKISTAN 45-A2 JOHAR TOWN LAHORE (2029-02)
	Application Form Dy. No / Tracking ID & date of submission	(YB2-AXP-LN64, 2026-01-22)
	Detail of Fee Submitted	313500, 2026-01-21,
	The proposed proprietary name / brand name	Bioaftogen SAT-1
	Label Claim	For active immunization of susceptible animals against Foot-and Mouth Disease
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	25dose vials of 2ml each-De-Controlled
	Shelf Life (Unit)	24 Monthstore below -4 to -8
	For generic drugs (me-too Status)	innovator
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogenesis Bago-RUTA PANAMERICANA km 38.5 (B1619IEA) GARÍN Province of BUENOS AIRES-Argentina
	Name, address of Marketing Authorization Holder:	Cloud Agri Pakistan, 228 A block C LDA phase 1, Lahore, Pakistan

Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
Evaluation Remarks	
The product is containing Sat-1 serotype of Foot and Mouth Disease virus. The matter of requirement of SAT-1 containing vaccine was referred to Ministry of National Food Security and following response was received from them: "The Disease Alert issued by this Ministry explicitly indicated that Pakistan is endemic with FMD A, O and Asia-1 serotypes whereas FMD SAT-1, SAT-2 and SAT-3 serotypes are not present and the country is officially free from these serotypes (Annex-I). A meeting of the Provincial Livestock Departments and a range of stakeholders including DCFA was convened under the chair of Animal Husbandry Commissioner on 22nd January 2026 to discuss the preparedness of the Provincial Livestock Departments and to deliberate on the need for vaccines. The minutes of the meeting along with the decisions taken are hyperlinked as Annex-II. Expert consensus during the meeting clearly concluded that prophylactic vaccination against FMDV SAT-1 is not required at this stage, as there is no laboratory-confirmed incursion of SAT-1 in Pakistan and uncertainty exists regarding the circulating topotypes in the region as it is challenging to determine which subtype (topotype I or topotype III) of SAT-1 may be introduced into the country. The meeting highlighted that import of SAT-1 vaccines carries inherent risks, including potential introduction of new virus strains, complications in disease surveillance due to vaccine-induced antibodies, and adverse implications for Pakistan's international trade and export certification. It was emphasized that WOAHP guidelines do not support routine vaccination against a serotype not currently circulating in the country and that vaccination decisions must be preceded by a formal risk assessment and antigenic matching with the circulating strain. The participants agreed that priority should be given to strengthening surveillance, diagnostics, and early detection, including procurement of SAT-1 diagnostic kits and confirmation of any suspected cases through the National Veterinary Laboratory. However, the meeting allowed that limited import of monovalent FMDV SAT-1 vaccine may be considered only for emergency outbreak response, under strict control of competent veterinary authorities (On the request of Provincial Livestock Departments) and not for commercial or general use." Registration Board in its 354th meeting on the basis of above recommendation decided the following for another SAT-1 containing vaccine: "Keeping in view the following recommendations of meeting of Provincial Livestock Departments and a range of stakeholders including DCFA convened under the chair of Animal Husbandry Commissioner on 22nd January 2026; Registration Board rejected the application: 1. Prophylactic vaccination against FMDV SAT-1 is not required at this stage, as there is no laboratory-confirmed incursion of SAT-1 in Pakistan and uncertainty exists regarding the circulating topotypes in the region as it is challenging to determine which subtype (topotype I or topotype III) of SAT-1 may be introduced into the country. 2. Import of SAT-1 vaccines carries inherent risks, including potential introduction of new virus strains, complications in disease surveillance due to vaccine-induced antibodies, and adverse implications for Pakistan's international trade and export certification. 3. WOAHP guidelines do not support routine vaccination against a serotype not currently circulating in the country and that vaccination decisions must be preceded by a formal risk assessment and antigenic matching with the circulating strain."	
Decision	
Rejected	
Keeping in view the following recommendations of meeting of Provincial Livestock Departments and a range of stakeholders including DCFA convened under the chair of Animal Husbandry Commissioner on 22nd January 2026; Registration Board rejected the application: 1. Prophylactic vaccination against FMDV SAT-1 is not required at this stage, as there is no laboratory-confirmed incursion of SAT-1 in Pakistan and uncertainty exists regarding the circulating topotypes in the region as it is challenging to determine which subtype (topotype I or topotype III) of SAT-1 may be introduced into the country.	

	2. Import of SAT-1 vaccines carries inherent risks, including potential introduction of new virus strains, complications in disease surveillance due to vaccine-induced antibodies, and adverse implications for Pakistan's international trade and export certification.	
	3. WOAHA guidelines do not support routine vaccination against a serotype not currently circulating in the country and that vaccination decisions must be preceded by a formal risk assessment and antigenic matching with the circulating strain.	
20	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	CLOUD AGRI PAKISTAN 45-A2 JOHAR TOWN LAHORE (2029-02)
	Application Form Dy. No / Tracking ID & date of submission	(XA6-2DU-NA6A, 2026-01-22)
	Detail of Fee Submitted	313500, 2026-01-21,
	The proposed proprietary name / brand name	Bioaftogen O+A+ASIA1+SAT1+SAT2
	Label Claim	for active immunization of susceptible animals against food and mouth disease
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled,200ml-De-Controlled,250ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	24 MonthStore and transport between 2 and 8°C.Do not freeze.
	For generic drugs (me-too Status)	innovator
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogenesis Bago-RUTA PANAMERICANA km 38.5 (B1619IEA) GARÍN Province of BUENOS AIRES-Argentina
	Name, address of Marketing Authorization Holder:	Cloud Agri Pakistan, 228 A block C LDA phase 1, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
Evaluation Remarks		
The product is containing Sat-1 serotype of Foot and Mouth Disease virus. The matter of requirement of SAT-1 containing vaccine was referred to Ministry of National Food Security and following response was received from them: "The Disease Alert issued by this Ministry explicitly indicated that Pakistan is endemic with FMD A, O and Asia-1 serotypes whereas FMD SAT-1, SAT-2 and SAT-3 serotypes are not present and the country is officially free from these serotypes (Annex-I). A meeting of the Provincial Livestock Departments and a range of stakeholders including DCFA was convened under the chair of Animal Husbandry Commissioner on 22nd January 2026 to discuss the preparedness of the Provincial Livestock Departments and to deliberate on the need for vaccines. The minutes of the meeting along with the decisions taken are hyperlinked as Annex-II. Expert consensus during the meeting clearly concluded that prophylactic vaccination against FMDV SAT-1 is not required at this stage, as there is no laboratory-confirmed incursion of SAT-1 in Pakistan and uncertainty exists regarding the circulating topotypes in the region as it is challenging to determine which subtype (topotype I or topotype III) of SAT-1 may be introduced into the country. The meeting highlighted that import of SAT-1 vaccines carries inherent risks, including potential introduction of new virus strains, complications in disease surveillance due to vaccine-induced antibodies, and adverse implications for Pakistan's international trade and export certification. It was emphasized that WOAHA guidelines do not support routine vaccination against a serotype not currently circulating in the country and that vaccination decisions must be preceded by a formal risk assessment and antigenic matching with the circulating strain. The participants agreed that priority should be given to strengthening surveillance, diagnostics, and early detection, including		

procurement of SAT-1 diagnostic kits and confirmation of any suspected cases through the National Veterinary Laboratory. However, the meeting allowed that limited import of monovalent FMDV SAT-1 vaccine may be considered only for emergency outbreak response, under strict control of competent veterinary authorities (On the request of Provincial Livestock Departments) and not for commercial or general use." Registration Board in its 354th meeting on the basis of above recommendation decided the following for another SAT-1 containing vaccine: "Keeping in view the following recommendations of meeting of Provincial Livestock Departments and a range of stakeholders including DCFA convened under the chair of Animal Husbandry Commissioner on 22nd January 2026; Registration Board rejected the application: 1. Prophylactic vaccination against FMDV SAT-1 is not required at this stage, as there is no laboratory-confirmed incursion of SAT-1 in Pakistan and uncertainty exists regarding the circulating topotypes in the region as it is challenging to determine which subtype (topotype I or topotype III) of SAT-1 may be introduced into the country. 2. Import of SAT-1 vaccines carries inherent risks, including potential introduction of new virus strains, complications in disease surveillance due to vaccine-induced antibodies, and adverse implications for Pakistan's international trade and export certification. 3. WOAHA guidelines do not support routine vaccination against a serotype not currently circulating in the country and that vaccination decisions must be preceded by a formal risk assessment and antigenic matching with the circulating strain."

Decision

Rejected

Keeping in view the following recommendations of meeting of Provincial Livestock Departments and a range of stakeholders including DCFA convened under the chair of Animal Husbandry Commissioner on 22nd January 2026; Registration Board rejected the application:

1. Prophylactic vaccination against FMDV SAT-1 is not required at this stage, as there is no laboratory-confirmed incursion of SAT-1 in Pakistan and uncertainty exists regarding the circulating topotypes in the region as it is challenging to determine which subtype (topotype I or topotype III) of SAT-1 may be introduced into the country.
2. Import of SAT-1 vaccines carries inherent risks, including potential introduction of new virus strains, complications in disease surveillance due to vaccine-induced antibodies, and adverse implications for Pakistan's international trade and export certification.
3. WOAHA guidelines do not support routine vaccination against a serotype not currently circulating in the country and that vaccination decisions must be preceded by a formal risk assessment and antigenic matching with the circulating strain.

21	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Macter International Limited F-216 S.I.T.E. Karachi-Pakistan. (022)
	Application Form Dy. No / Tracking ID & date of submission	(3PZ-BVQ-WB25, 2025-06-28)
	Detail of Fee Submitted	300000.0, 2025-04-03,
	The proposed proprietary name / brand name	Denomab 60mg Solution for Injection in Pre-filled Syringe
	Label Claim	Each pre-filled syringe (1ml) contains: Denosumab.....60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Stored at 2°C to 8°C
	For generic drugs (me-too Status)	PROLIA by M/s. Amgen Manufacturing Limited, Juncos, Puerto Rico, USA. Imported by GlaxoSmithKline, Karachi.
	Pharmacotherapeutic Group of (API)	Monoclonal Antibody

	Name, address of Manufacturing site:	Intas Pharmaceuticals Limited-Plot No. 423 / P A Gide Sarkhej Moraiya 382 213 India.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity data submitted.
	Name, address of Marketing Authorization Holder:	Macter International Limited , F-216 & F-217-A, S.I.T.E, Karachi-Pakistan., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	EMA CoPP No. 01/26/000531 dated 111689
	Details of Authorization Letter :	Scanned LOA dated 06-04-2026.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: P23.1-BM-0011, P23.1-BM-0012, P23.1-BM-0010 Conditions: 2-8C Frequency: 0, 3, 6, 9, 12, 18, 24 months.
	The status in reference regulatory authorities	FDA & EMA
	Evaluation Remarks	
	The firm has submitted EMA CoPP of Osvyrti 60 mg indicating proposed manufacturer as one of the manufacturers.	
	Decision	
	Approved	
	Keeping in view EMA issued CoPP indicating product availability in European countries; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of valid legalized EMA issued CoPP.	
22	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Macter International Limited F-216 S.I.T.E. Karachi-Pakistan. (022)
	Application Form Dy. No / Tracking ID & date of submission	(2NB-HD5-PWE9, 2026-04-01)
	Detail of Fee Submitted	313500, 2025-12-05,
	The proposed proprietary name / brand name	Denomab 120mg Solution for Injection
	Label Claim	Each vial (1.7ml) contains: Denosumab.....120mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's vial-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2°C – 8°C).
	For generic drugs (me-too Status)	XGEVA 120 mg/1.7 ml solution for injection M/s. Amgen Manufacturing Limited, Juncos, Puerto Rico, USA. Imported by GlaxoSmithKline, Karachi.
	Pharmacotherapeutic Group of (API)	Monoclonal Antibody
	Name, address of Manufacturing site:	Intas Pharmaceuticals Limited-Plot No. 423 / P / A Sarkhej Bavla Highway, Village- Moraiya, Tal-Sanand, Dist. Ahmedabad- 382 213, Gujrat State, INDIA-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity data submitted.
	Name, address of Marketing Authorization Holder:	Macter International Ltd., F-216 S.I.T.E., Karachi., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	EMA CoPP No. 01/26/000532 dated 111689
	Details of Authorization Letter :	Scanned LOA dated 06-04-2026.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: P23.1-BM-0011, P23.1-BM-0012, P23.1-BM-0010 Conditions: 2-8C Frequency: 0,

		3, 6, 9, 12, 18, 24 months.
	The status in reference regulatory authorities	Xgeva (denosumab) 120 mg/1.7 ml solution for injection By Amgen Inc. (USFDA Approved)
	Evaluation Remarks	
	The firm has submitted EMA CoPP of Jubereq 120 mg indicating proposed manufacturer as one of the manufacturers.	
	Decision	
	Approved	
	Keeping in view EMA issued CoPP indicating product availability in European countries; Registration Board approved the product subject to compliance of current Import Policy for finished drugs, submission of valid legalized EMA issued CoPP and change of brand name.	
23	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Genix Pharma (Pvt) Ltd , Plot No. 44-45-B, Korangi Creek Road, Karachi (0640)
	Application Form Dy. No / Tracking ID & date of submission	(ZN8-6W1-HN3Q, 2026-04-15)
	Detail of Fee Submitted	300000.0, 2025-07-15,
	The proposed proprietary name / brand name	ADALIMOMAB
	Label Claim	Each 0.4 ml single dose of pre-filled syringe contains: Adalimumab.....40 mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x1's-As per SRO
	Shelf Life (Unit)	2 YearsStore between + 2°C and + 8°C
	For generic drugs (me-too Status)	Schazoo Pharmaceutical Laboratories(Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Shilpa Biologicals Private Limited-Plot 532-A, Belur Industrial Area, Dharwad, Karnataka, India,580011.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Genix Pharma (Pvt) Ltd. Karachi, 44,45-B Korangi Creek Road, Karachi 75190 Pakistan , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	AbbVie Inc. North Chicago, IL 60064 U.S.A.
	Evaluation Remarks	
	The same product from same manufacturer is already approved in name of M/s Martin Dow Marker Limited, Karachi in 351st meeting of Registration Board. The applicant was asked for clarification and they submitted a digitally signed LOA from Shilpa Biologicals Private Limited, India. Following email has already been sent to the manufacturer abroad on 06-04-2026: "two different importers/ indenters have applied for registration of subject mentioned Biological Drug in Pakistan proposed to be imported from M/s Shilpa Biologicals Private Limited, Plot 532-A, Belur Industrial Area, Dharwad, Karnataka, India:1. M/s Martin Dow Marker Limited, Karachi.2. M/s Genix Pharma, Karachi. It is pertinent to mention that both the agents have submitted Letter of Authorizations (LOAs) in their name from above said manufacturer. M/s Martin Dow Marker Limited, Karachi has provided scanned legalized LOA duly signed by Mr. Balaji Sunkara while M/s Genix Pharma, Karachi has provided scanned LOA digitally signed by Mr. Balaji Sunkara. As per	

prevailing policy for registration of drugs in Pakistan, only one importer/ indenter can import a drug from particular manufacturer. Hence, it is requested to confirm which of the above mentioned importers/ indenters is sole authorization holder of M/s Shilpa Biologicals Private Limited, Plot 532-A, Belur Industrial Area, Dharwad, Karnataka, India for registration of subject mentioned Biological Drug in Pakistan." The response of email is still awaited.

Decision

Deferred

Registration Board decided to ask M/s Martin Dow Marker Limited, Karachi for clarification regarding authorization of M/s Genix Pharma (Pvt.) Ltd., Karachi for Adalimumab 40mg Injection manufactured by M/s Shilpa Biologicals Private Limited, India already approved in name of M/s Martin Dow Marker Limited, Karachi in 351st meeting of Registration Board.

24	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Snam Pharma 61-G, Phase 1, Commercial Area, DHA, Lahore (05-352-0058-036985D)
	Application Form Dy. No / Tracking ID & date of submission	(Y66-A52-UU9W, 2025-10-24)
	Detail of Fee Submitted	313500, 2025-10-24,
	The proposed proprietary name / brand name	RINBIO ND Newcastle Disease Virus Vaccine, Live (Strain La Sota)
	Label Claim	Each dose contains: Newcastle disease virus, strain La Sota..... $\geq 10^{6.0}$ EID ₅₀
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000 doses x 10 Vials-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store at 2°C - 8°C
	For generic drugs (me-too Status)	Same Formulation already registered in Pakistan
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Ringpu (Baoding) Biological Pharmaceutical Co. Ltd-No.793, Tengfei Road, Baoding Industry Area, Baoding City, Hebei Province-China
	Name, address of Marketing Authorization Holder:	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 03022 dated 11-05-2023 valid till 31-05-2027. Scanned Apostille FSC No. Hebei (2025) 020 dated 05-06-2025 valid till 24-01-2026.
	Details of Authorization Letter :	Scanned Apostille Authorization letter from 25-05-2025 to 24-05-2030.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
Evaluation Remarks		
Initially the firm mentioned Thermostable vaccine in their dossier and same was indicated in FSC. On query, the firm submitted that it's only the brand name of product and their vaccine is stable at 2-8C as per submitted stability data. The firm submitted Export Certificate of Animal drugs indicating product availability in country of export instead of FSC which was valid at the time of submission and is now expired.		
Decision		
Approved		

	Keeping in view Export Certificate of Animal drugs indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of revised valid legalized FSC indicating correct description of vaccine.	
25	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	(MR6-5LH-HWAV, 2025-09-19)
	Detail of Fee Submitted	313500, 2025-09-17,
	The proposed proprietary name / brand name	RINBIO IB Avian Infectious Bronchitis Vaccine, Live (H120 Strain)
	Label Claim	Each dose contains: Infectious Bronchitis virus fluid (strain H120)..... $\geq 10^{3.6}$ EID ₅₀
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000 doses x 10 Vials-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store at 2°C - 8°C
	For generic drugs (me-too Status)	Same Formulation already registered in Pakistan
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Ringpu (Baoding) Biological Pharmaceutical Co. Ltd-No.793, Tengfei Road, Baoding Industry Area, Baoding City, Hebei Province,-China
	Name, address of Marketing Authorization Holder:	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 03022 dated 11-05-2023 valid till 31-05-2027. Scanned Apostille FSC No. Hebei (2025) 020 dated 05-06-2025 valid till 24-01-2026.
	Details of Authorization Letter :	Scanned Apostille Authorization letter from 25-05-2025 to 24-05-2030.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
Evaluation Remarks		
Initially the firm mentioned Thermostable vaccine in their dossier and same was indicated in FSC. On query, the firm submitted that it's only the brand name of product and their vaccine is stable at 2-8C as per submitted stability data. The firm submitted Export Certificate of Animal drugs indicating product availability in country of export instead of FSC which was valid at the time of submission and is now expired.		
Decision		
Approved		
Keeping in view Export Certificate of Animal drugs indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of revised valid legalized FSC indicating correct description of vaccine.		
26	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	(LBT-UYH-U58J, 2025-09-19)
	Detail of Fee Submitted	313500, 2025-09-17,
	The proposed proprietary name / brand name	RINBIO ND+IB Newcastle Disease and Infectious Bronchitis Vaccine, Live (Strain La Sota + Strain H120)
	Label Claim	Each dose of vaccine contains: Newcastle disease virus fluid (strain La Sota)..... $\geq 10^{6.5}$ EID ₅₀ Infectious Bronchitis virus fluid, (strain H120)..... $\geq 10^{3.5}$ EID ₅₀ *EID ₅₀ =50% Embryo Infection Dose
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000 doses x 10 Vials-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store at 2°C - 8°C
	For generic drugs (me-too Status)	Same Formulation already registered in Pakistan
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Ringpu (Baoding) Biological Pharmaceutical Co. Ltd-No.793, Tengfei Road, Baoding Industry Area, Baoding City, Hebei Province,-China
	Name, address of Marketing Authorization Holder:	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 03022 dated 11-05-2023 valid till 31-05-2027. Scanned Apostille FSC No. Hebei (2025) 020 dated 05-06-2025 valid till 24-01-2026.
	Details of Authorization Letter :	Scanned Apostille Authorization letter from 25-05-2025 to 24-05-2030.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	Initially the firm mentioned Thermostable vaccine in their dossier and same was indicated in Export Certificate of Animal drugs. On query, the firm submitted that it's only the brand name of product and their vaccine is stable at 2-8C as per submitted stability data. The firm submitted Export Certificate of Animal drugs indicating product availability in country of export instead of FSC which was valid at the time of submission and is now expired.	
27	Decision	
	Approved	
	Keeping in view Export Certificate of Animal drugs indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of revised valid legalized FSC indicating correct description of vaccine.	
	Case Category	Routine (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) $\geq 10^{2.5}$ TCID50 2 Feline Calicivirus $\geq 10^{2.5}$ TCID50 3 Feline Panleukopenia virus $\geq 10^{2.5}$ 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 (Na ₂ HPO ₄ *2H ₂ O 11,5 mg Potassium hydrogen phosphate (KH ₂ P04) 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 Month 2~8 °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 firm then submitted a published study of some other vaccine. On query, the firm submitted that "The already submitted Efficacy/Potency study for Felinevac 3 might have the resemblance with mentioned journal because that is a prototype study with same vaccine formulation , therefore pharmaceutical companies do follow this study for accuracy of their commercial vaccine study. Due to your concern for previous study, we do hereby providing another Potency test performed for our vaccine Feline vac 3." The provided study is a four pages document where in it was mentioned that study was performed in Doğuvet Veterinary Clinic on 23 animals and antibody Titre was checked by the firm after 28 days of 1 dose of administration. The firm has named this 23 animal study a field trial. Moreover, safety studies are not performed by the firm.	
28	Decision	
	Deferred	
	Registration Board referred the case to Expert Working Group on Veterinary Drugs for recommendations on Safety and Efficacy data provided by the firm.	
	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	(S42-XXT-JXSD, 2026-04-20)

Detail of Fee Submitted	38700, 2026-02-03,
The proposed proprietary name / brand name	Sematide 8mg/3ml Injection
Label Claim	Each Prefilled Pen (3ml) contains: Semaglutide.....8mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	24 Year(s)Store in the refrigerator (2°C to 8°C). Do not freeze.
For generic drugs (me-too Status)	Ozempic 8mg/3mL
Pharmacotherapeutic Group of (API)	GLP-1 receptor agonist
Name, address of Manufacturing site:	Self Manufacturing
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence submitted.
Name, address of Marketing Authorization Holder:	, ,
Details of Certificates (CoPP/FSC/cGMP):	The firm has got Section approval on 24-03-2026.
Details of Authorization Letter :	Clearance Certificate No. RO-64328C dated 23-12-2024 is submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: G06210801, G06210901, G06210902 Conditions: 2-8C Frequency: 0,1,2,3,6 moths Accelerated & 0,3,6,9,12,18, 24 & 36 months Real Time
The status in reference regulatory authorities	OZEMPIC 8mg/3mL (NOVO NORDISK)
Evaluation Remarks	
The drug substance shall be imported from Zhejiang Peptides Biotech Co., Ltd. China. The firm already has registrations of different strengths in different container closure for the same API.	
Decision	
Approved	
The Registration Board approved application with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.	

	6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
29	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	(QT6-RBR-1BZB, 2026-04-20)
	Detail of Fee Submitted	38700, 2026-02-03,
	The proposed proprietary name / brand name	Sematide 2mg/3ml Injection
	Label Claim	Each Prefilled Pen (3ml) contains: Semaglutide.....2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store between 2°C to 8°C
	For generic drugs (me-too Status)	Sem-P (Getz Pharma)
	Pharmaceutical Group of (API)	GLP-1 receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd.
	Detail of stability batches of drug product	Three Batches: 098D01, 098D02, 098D03 Size: 200 Cartridges Each Conditions: 2-8C Frequency: 0,3,6 months Accelerated & 0,3,6, months Real Time
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate No. RO-64328C dated 23-12-2024 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: G06210801, G06210901, G06210902 Conditions: 2-8C Frequency: 0,1,2,3,6 moths Accelerated & 0,3,6,9,12,18, 24 & 36 months Real Time
	The status in reference regulatory authorities	OZEMPIC 2mg/3mL (NOVO NORDISK)
	GMP status of the firm	The firm has got Section approval on 24-03-2026.
	Evidence of approval of manufacturing facility	The firm has got Section approval on 24-03-2026.
Evaluation Remarks		
The drug substance shall be imported from Zhejiang Peptides Biotech Co., Ltd. China. The firm already has registrations of different strengths in different container closure for the same API.		
Decision		
Approved		
The Registration Board approved application with following conditions:		
1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.		
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.		

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

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

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

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

30	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	(8HY-SJD-HL7Y, 2026-04-20)
	Detail of Fee Submitted	38700, 2026-01-22,
	The proposed proprietary name / brand name	Sematide 4mg/3ml Injection
	Label Claim	Each Prefilled Pen (3ml) contains Semaglutide.....4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store between 2°C to 8°C
	For generic drugs (me-too Status)	Sem-P (Getz Pharma)
	Pharmacotherapeutic Group of (API)	GLP-1 receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd.
	Detail of stability batches of drug product	Three Batches: 085D01, 085D02, 085D03 Size: 200 Cartridges Each Conditions: 2-8C Frequency: 0,3,6 months Accelerated & 0,3,6, months Real Time
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate No. RO-64328C dated 23-12-2024 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: G06210801, G06210901, G06210902 Conditions: 2-8C Frequency: 0,1,2,3,6 moths Accelerated & 0,3,6,9,12,18, 24 & 36 months Real Time
	The status in reference regulatory authorities	OZEMPIC 4mg/3mL (NOVO NORDISK)
	GMP status of the firm	The firm has got Section approval on 24-03-2026.
	Evidence of approval of manufacturing facility	The firm has got Section approval on 24-03-2026.
Evaluation Remarks		
The drug substance shall be imported from Zhejiang Peptides Biotech Co., Ltd. China. The firm already has registrations of different strengths in different container closure for the same API.		
Decision		
Approved		
The Registration Board approved application with following conditions:		

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

31	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	(QSD-7YR-MZ6B, 2026-03-24)
	Detail of Fee Submitted	38700, 2026-02-20,
	The proposed proprietary name / brand name	Sematide 6.8mg/3ml Injection
	Label Claim	Each Pre-filled pen (3mL) contains: Semaglutide.....6.8mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	24 Year(s)Store at 2°C and 8°C
	For generic drugs (me-too Status)	Wegovy 6.8mg/3mL (NOVO NORDISK)
	Pharmaceutical Group of (API)	GLP-1 receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd.
	Detail of stability batches of drug product	Three Batches: 099D01, 099D02, 099D03 Size: 200 Cartridges Each Conditions: 2-8C Frequency: 0,3,6 months Accelerated & 0,3,6, months Real Time
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate No. RO-64328C dated 23-12-2024 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: G06210801, G06210901, G06210902 Conditions: 2-8C Frequency: 0,1,2,3,6 moths Accelerated & 0,3,6,9,12,18, 24 & 36 months Real Time
	The status in reference regulatory authorities	Wegovy 6.8mg/3mL (NOVO NORDISK)
	GMP status of the firm	The firm has got Section approval on 24-03-2026.

Evidence of approval of manufacturing facility	The firm has got Section approval on 24-03-2026.
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Evaluation Remarks

The drug substance shall be imported from Zhejiang Peptides Biotech Co., Ltd. China. The firm already has registrations of different strengths in different container closure for the same API. The firm has registration of Sematide brand name for their already registered Semaglutide strengths which were similar to Ozempic strengths, however, the applied strength is a strength of Innovator product Wegovy, hence, brand name shall be changed.

Decision

Approved

The Registration Board approved application with following conditions and change of brand name:

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 (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	(G3N-PSP-MR68, 2026-03-24)
	Detail of Fee Submitted	38700, 2026-02-20,
	The proposed proprietary name / brand name	Sematide 9.6mg/3ml Injection
	Label Claim	Each Prefilled Pen (3ml) contains: Semaglutide.....9.6mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	24 Year(s)Store at 2°C and 8°C
	For generic drugs (me-too Status)	Wegovy 9.6mg/3mL (NOVO NORDISK)
	Pharmacotherapeutic Group of (API)	GLP-1 receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd.
	Detail of stability batches of drug product	Three Batches: 100D01, 100D02, 100D03 Size: 200 Cartridges Each Conditions: 2-8C Frequency:

		0,3,6 months Accelerated & 0,3,6, months Real Time
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate No. RO-64328C dated 23-12-2024 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: G06210801, G06210901, G06210902 Conditions: 2-8C Frequency: 0,1,2,3,6 months Accelerated & 0,3,6,9,12,18, 24 & 36 months Real Time
	The status in reference regulatory authorities	Wegovy 9.6mg/3mL (NOVO NORDISK)
	GMP status of the firm	The firm has got Section approval on 24-03-2026.
	Evidence of approval of manufacturing facility	The firm has got Section approval on 24-03-2026.
	Evaluation Remarks	
	The drug substance shall be imported from Zhejiang Peptides Biotech Co., Ltd. China. The firm already has registrations of different strengths in different container closure for the same API. The firm has registration of Sematide brand name for their already registered Semaglutide strengths which were similar to Ozempic strengths, however, the applied strength is a strength of Innovator product Wegovy, hence, brand name shall be changed.	
	Decision	
	Approved	
	The Registration Board approved application with following conditions and change of brand name:	
	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 (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	(MAM-YRH-4PMV, 2024-07-26)
	Detail of Fee Submitted	300000.0, 2024-07-24,

	The proposed proprietary name / brand name	CLOTEAN suspension for injection Serum against tetanus
	Label Claim	Composition - 1 ml: Immunoserum tetanicum equinum nativum min. 300 IU
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	20ml x 5-De-Controlled
	Shelf Life (Unit)	2 Year(s)2 – 8 °C
	For generic drugs (me-too Status)	Not registered
	Pharmacotherapeutic Group of (API)	Veterinary Immunoglobulins
	Name, address of Manufacturing site:	Bioveta, a.s.-Komenského 212/12, 683 23 Ivanovice na Hané Czech Republic-Czechia
	Name, address of Marketing Authorization Holder:	Bioveta, a.s., Komenského 212/12, 683 23 Ivanovice na Hané Czech Republic, Czechia
	Details of Certificates (CoPP/FSC/cGMP):	Valid legalized CoPP has been submitted.
	Details of Authorization Letter :	Legalized POA 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	
	Registration Board in its 347th meeting decided as follows: "The Registration Board endorsed the recommendations of sub-committee on veterinary drugs and deferred the case for the opinion of M/o National Food Security & Research regarding immunological relevance and need of applied product in Pakistan." EWG in its 9th meeting considered the data provided by the firm and decided to recommend the product for grant of registration.	
	Decision	
	Approved	
	Keeping in view the recommendations of Expert Working Group on Veterinary Drugs and FSC indicating product availability in country of origin; Registration board approved the product subject to compliance of current Import Policy for finished drugs.	
34	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Vetline International 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore (05-352-0066-040712D)
	Application Form Dy. No / Tracking ID & date of submission	(VEJ-6Y9-DVB3, 2024-07-23)
	Detail of Fee Submitted	300000.0, 2024-07-11,
	The proposed proprietary name / brand name	Biocan Novel DHPPi/L4, lyophilizate and suspension for injection for dogs
	Label Claim	Each dose (1 ml) contains: Lyophilisate (live attenuated): Canine Distemper virus, strain CDV Bio 11/A $10^{3.1}$ TCID _{min} . $10^{5.1}$ TCID _{max} , Canine Adenovirus type 2, strain CAV-2 Bio 13 $10^{3.6}$ TCID _{min} . $10^{5.3}$ TCID _{max} , Canine Parvovirus type 2b, strain CPV-2b Bio 12/B $10^{4.3}$ TCID _{min} . $10^{6.6}$ TCID _{max} , Canine Parainfluenza type 2 virus, strain CPiV-2 Bio 15 $10^{3.1}$ TCID _{min} . $10^{5.1}$ TCID _{max} . Suspension (inactivated): Leptospira interrogans serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae, strain MSLB 1089 GMT $\geq$ 1:51 ALR, Leptospira interrogans serogroup Canicola serovar Canicola, strain MSLB 1090 GMT $\geq$ 1:51 ALR, Leptospira kirschneri serogroup Grippotyphosa serovar

		Grippytyphosa, strain MSLB 1091 GMT $\geq$ 1:40 ALR & Leptospira interrogans serogroup Australisserovar Bratislava, strain MSLB 1088 GMT $\geq$ 1:51 ALR
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10x1ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)2 – 8 °C
	For generic drugs (me-too Status)	Not registered
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Bioveta, a.s.-Komenského 212/12, 683.23 Ivanovice na Hané Czech Republic-Czechia
	Name, address of Marketing Authorization Holder:	Bioveta, a.s., Komenského 212/12, 683.23 Ivanovice na Hané Czech Republic, Czechia
	Details of Certificates (CoPP/FSC/cGMP):	Valid legalized CoPP has been submitted.
	Details of Authorization Letter :	Legalized POA 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	
	Registration Board in its 347th meeting decided as follows: "The Registration Board endorsed the recommendations of sub-committee on veterinary drugs and deferred the case for the opinion of M/o National Food Security & Research regarding immunological relevance and need of applied product in Pakistan." EWG in its 9th meeting considered the data provided by the firm and decided to recommend the product for grant of registration.	
	Decision	
	Approved	
	Keeping in view the recommendations of Expert Working Group on Veterinary Drugs and CoPP indicating product availability in country of origin; Registration board approved the product subject to compliance of current Import Policy for finished drugs and change of brand name.	
35	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Vetline International 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore (05-352-0066-040712D)
	Application Form Dy. No / Tracking ID & date of submission	(ZAJ-TTV-2VZJ, 2024-07-26)
	Detail of Fee Submitted	300000.0, 2024-07-24,
	The proposed proprietary name / brand name	Biocan Novel DHPPi, lyophilizate and solvent for suspension for injection for dogs
	Label Claim	Each dose (1 ml) contains : Lyophilisate (live attenuated): Canine Distemper virus, strain CDV Bio 11/A $10^{3.1}$ TCID min. $10^{5.1}$ TCID max Canine Adenovirus type 2, strain CAV-2 Bio 13 $10^{3.6}$ TCID min. $10^{5.3}$ TCID max Canine Parvovirus type 2b, strain CPV-2b Bio 12/B $10^{4.3}$ TCID min. $10^{6.6}$ TCIDmax Canine Parainfluenza type 2 virus, strain CPiV-2 Bio 15 $10^{3.1}$ TCID min. $10^{5.1}$ TCID max. Solvent: Water for Injection
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1ml x 10-De-Controlled
	Shelf Life (Unit)	2 Year(s)2 – 8 °C
	For generic drugs (me-too Status)	Not registered
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine

	Name, address of Manufacturing site:	Bioveta, a.s.,-Komenskeho 212/12, 683 23 Ivanovice na Bane Czech Republic-Czechia
	Name, address of Marketing Authorization Holder:	Bioveta, a.s., Komenskeho 212/12, 683 23 Ivanovice na Bane Czech Republic, Czechia
	Details of Certificates (CoPP/FSC/cGMP):	Valid legalized CoPP has been submitted
	Details of Authorization Letter :	Legalized POA 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	
	Registration Board in its 347th meeting decided as follows: "The Registration Board endorsed the recommendations of sub-committee on veterinary drugs and deferred the case for the opinion of M/o National Food Security & Research regarding immunological relevance and need of applied product in Pakistan." EWG in its 9th meeting considered the data provided by the firm and decided to recommend the product for grant of registration.	
	Decision	
	Approved	
	Keeping in view the recommendations of Expert Working Group on Veterinary Drugs and CoPP indicating product availability in country of origin; Registration board approved the product subject to compliance of current Import Policy for finished drugs and change of brand name.	
36	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Vetline International 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore (05-352-0066-040712D)
	Application Form Dy. No / Tracking ID & date of submission	(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." EWG in its 9th meeting considered the data provided by the firm and decided to refer the case to M/s NFS&R for their comments regarding Need and Presence of H5N8 in Pakistan.

Decision

Deferred

Keeping in view the recommendations of Expert Working Group on Veterinary Drugs; Registration board referred the case of Ministry of National Food Security & Research for their comments regarding presence of circulating H5N8 strain and need of its vaccine for Pakistan.

37	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	(5XU-434-VEW1, 2025-10-30)
	Detail of Fee Submitted	313500, 2025-10-24,
	The proposed proprietary name / brand name	RINVAC MG
	Label Claim	RINVAC MG - Mycoplasma Gallisepticum Vaccine, Inactivated - Strain CR antigen before inactivation $\geq 10^9$ ccu/ml - Details as per attached Label.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500 ml/Bottle-De-Controlled
	Shelf Life (Unit)	24 MonthStore at 2°C - 8°C
	For generic drugs (me-too Status)	Same Formulation already registered in Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Ringpu (Baoding) Biological Pharmaceutical Co. Ltd-No. 793, Tengfei Road, Baoding Industry Area, Baoding City, Hebei Province-China
	Name, address of Marketing Authorization Holder:	Tianjin Ringpu Bio-Technology Co., Ltd., No. 1 Dongjiu Road, Tianjin Free Trade Area (Airport Economic Area), Tianjin, China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	EWG in its 9th meeting considered the data provided by the firm and decided to recommend the product for grant of registration.	
38	Decision	
	Approved	
	Keeping in view recommendation of Expert Working Group on Veterinary Drugs and Export Certificate of Animal drugs indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of valid legalized FSC.	
	Case Category	Routine (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 9th meeting considered decided to ask the firm to provide details, immunological relevance and need of applied strain for Pakistan. Following are the observations in application: Real time stability data provided is of one experimental scale batch for 06 months. FSC is from Chamber of Commerce for which the firm has submitted a reference of law and weblink from country of origin but weblink is not accessible.	
39	Decision	
	Deferred	
	Keeping in view the recommendations of Expert Working Group on Veterinary Drugs; Registration board deferred the case for submission of following by the firm:	
	1. Immunological relevance and need of applied strain for Pakistan. 2. Stability data of three commercial batches of vaccine up to the proposed shelf life.	
	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Inouko Animal Health (Private) Limited 3rd Floor, Plaza No. 3, D-Block, DHA Phase 5, Cantt, District Lahore (05-352-0058-043305D)
	Application Form Dy. No / Tracking ID & date of submission	(ZUP-8TV-496V, 2025-06-27)
	Detail of Fee Submitted	300000.0, 2025-06-03,

	The proposed proprietary name / brand name	Coglavax Clostridium Perfringens Vaccine, Inactivated
	Label Claim	Each ml contains: Clostridium perfringens α -antitoxin.....2 IU Clostridium perfringens β -antitoxin.....10.0 IU Clostridium perfringens ϵ -antitoxin.....5.0 IU Clostridium septicum antitoxin.....2.5 IU Clostridium novyi B antitoxin.....3.5 IU Clostridium tetani antitoxin.....2.5 IU Anaculture of Clostridium chauvoei.....min. 90 % protection
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	50, 100, 250, 500 ml.-De-Controlled
	Shelf Life (Unit)	24 Month(s)The product must be stored between +2°C and +8°C protected from light.
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Inactivated Bacterial Vaccine
	Name, address of Manufacturing site:	CEVA-PHYLAXIA VETERINARY BIOLOGICALS CO. LTD,-1107 Budapest, Szállás u. 5., Hungary -Hungary
	Name, address of Marketing Authorization Holder:	CEVA-PHYLAXIA VETERINARY BIOLOGICALS CO. LTD,, 1107 Budapest, Szállás u. 5., Hungary , Hungary
	Details of Certificates (CoPP/FSC/cGMP):	Copy of Apostille GMP Certificate Reference: 5300/20622-3/2024 dated 16-02-2024. Copy of Apostille Free Sale Certificate Reference: 5300/20622-2/2024 dated 16-02-2024.
	Details of Authorization Letter :	Copy of Power of Attorney 11-10-2023.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batches: 100140, 100142, 100144 Size: 30 Litres, 200 Litre, 200 Litre Conditions: 2C-8C Duration: 27 Months Frequesncy: 0, 9, 15, 18, 21, 24, 27
	Evaluation Remarks	
	EWG in its 9th meeting considered the data provided by the firm and decided to recommend the product for grant of registration.	
	Decision	
	Approved	
	Keeping in view recommendation of Expert Working Group on Veterinary Drugs and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
40	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Vetline International 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore (05-352-0066-040712D)
	Application Form Dy. No / Tracking ID & date of submission	(PSR-595-4GMD, 2025-09-17)
	Detail of Fee Submitted	313500, 2025-09-15,
	The proposed proprietary name / brand name	QVAC ND+IB+H9+G

	Label Claim	This vaccine contains: Inactivated Newcastle disease virus (La Sota) $\geq 4 \times 108.0 \text{EID}_{50}/0.1 \text{ml}$ before inactivation, Inactivated Infectious Bronchitis virus (M41) $\geq 4 \times 106.0 \text{EID}_{50}/0.1 \text{ml}$ before inactivation, Inactivated H9 subtype avian influenza virus (SZ Strain) $\geq 4 \times 108.0 \text{EID}_{50}/0.1 \text{ml}$ before inactivation, Infectious Bursal Disease (Protein rVP2) AGP titer $\geq 1:64$ (equals to $6 \log 2$)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	500ml-De-Controlled
	Shelf Life (Unit)	24 Year(s) 2-8°C
	For generic drugs (me-too Status)	1. GPVAC ND+IB+IBD 2. GPVAC ND+IB+H9 3. Medivac ND-IB-IBD Emulsion 4. Winvac Newcastle Bronchitis Gumboro Vaccine 5. Innovax ND-IBD
	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	
41	Keeping in view the recommendations of EWG; Registration Board in its 352nd meeting deferred the case for submission of following by the firm: Scanned copy of legalized/ Apostille Product Specific Letter of Authorization from manufacturer abroad? Scanned copy of revised FSC indicating actual status of availability of product in country of origin instead of only indicating permission to be sold? Details & relevance of strains. The firm has submitted Apostille LOA from QYH Biopharmaceutical. Apostille FSC indicating availability of product in country of origin. EWG in its 9th meeting considered the data provided by the firm and decided to recommend the product for grant of registration.	
	Decision	
	Approved	
	Keeping in view recommendation of Expert Working Group on Veterinary Drugs and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of Apostille/Legalized letter from Product License holder in country of origin indicating that M/s QYH Biopharmaceutical is authorized for issuance of LOA from its behalf..	
	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Grand Pharma Pvt Ltd Plot no 5-A , Street No N-5 , National Industrial Zone Rawat Islamabad (000680)
	Application Form Dy. No / Tracking ID & date of submission	(8PS-ZMY-89XU, 2025-07-12)
	Detail of Fee Submitted	37000.0, 2025-07-10,
	The proposed proprietary name / brand name	BVD-HERPES SHIELD

	Label Claim	Each 2 ml dose contains: Infectious Bovine Rhinotracheitis Virus Type-1 Antigen (Glycoprotein B)..100 Microgram Bovine Viral Diarrhea Virus Type-1 Antigen (E 2 Protein) 100 Microgram Bovine Viral Diarrhea Virus Type-2 Antigen (E 2 Protein) 100 Microgram
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	20ml-De-Controlled
	Shelf Life (Unit)	2 Year2c to 8c
	For generic drugs (me-too Status)	Hiprabovis-4 Hipra Laboratories, Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Keeping in view the above stated facts, the Panel unanimously agreed to recommend renewal of DML No.000680 (Formulation} for further period of five years as per under mentioned sections In the light of Tracking ID TN9-LVX-GDZI dated 16th May 2025 by Direc
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Keeping in view the recommendations of EWG; Registration Board in its 352 meeting deferred the case for submission of following by the firm: "Immunological relevance & need of applied Virus infections in Pakistan." EWG in its 9th meeting considered the data provided by the firm and decided to recommend the product for grant of registration.	
	Decision	
	Approved	
	Keeping in view recommendation of Expert Working Group on Veterinary Drugs; Registration Board approved the product.	
42	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Grand Pharma Pvt Ltd Plot no 5-A , Street No N-5 , National Industrial Zone Rawat Islamabad (000680)
	Application Form Dy. No / Tracking ID & date of submission	(ZHZ-TDT-8WR9, 2025-07-14)
	Detail of Fee Submitted	37000.0, 2025-07-10,
	The proposed proprietary name / brand name	MycoBovis Shield
	Label Claim	Each dose of 2 ml contains: Inactivated Mycoplasma bovis 1.6 x 10 ⁹ CFU
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	20ml-De-Controlled
	Shelf Life (Unit)	2 Year2c to 8c
	For generic drugs (me-too Status)	Mycoplasma bovis bacterin (Myco B One Dose) American Animal Health, Inc. Grand Prairie, TX 75052-U.S.A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Keeping in view the above stated facts, the Panel unanimously agreed to recommend renewal of DML No.000680 (Formulation} for further period of five years as per under mentioned

		sections In the light of Tracking ID TN9-LVX-GDZI dated 16th May 2025 by Direc
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Keeping in view the recommendations of EWG; Registration Board deferred the case for submission of following by the firm: "Details & relevance of strain." EWG in its 9th meeting considered the data provided by the firm and decided to recommend the product for grant of registration.	
	Decision	
	Approved	
	Keeping in view recommendation of Expert Working Group on Veterinary Drugs; Registration Board approved the product.	
43	Case Category	Routine (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) $\geq 10^6.0\text{EID}_{50}$ / dose, Infectious Bronchitis Virus (K1277/03 P90 strain) $\geq 10^3.0\text{EID}_{50}$ / 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	
	Keeping in view the recommendations of EWG; Registration Board in its 352nd meeting deferred the case for submission of following by the firm: "Immunological relevance data for need of K1277/03 P90 strain in Pakistan as strain is locally not reported." EWG in its 9th meeting considered the data provided by the firm and decided to ask the firm to provide detailed studies of K1277/03 P90 strains regarding its similarity to existing strains of Pakistan.	
	Decision	
	Deferred	

	Keeping in view the recommendations of Expert Working Group on Veterinary Drugs; Registration board deferred the case for submission of detailed studies of K1277/03 P90 strain regarding its similarity to existing strains of Pakistan.	
44	Case Category	Routine (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) $\geq 10^{3.0}$ EID ₅₀ / dose at release
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	2000 Dose/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, Saengmyeonggwahakgwang-gil, Hongcheon-eup, Hongcheon-gun, Gangwon-do, Republic of Korea-South
	Name, address of Marketing Authorization Holder:	CTCVAC Co., Ltd., 106, Saengmyeonggwahakgwang-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	
	Keeping in view the recommendations of EWG; Registration Board in its 352nd meeting deferred the case for submission of following by the firm: "Immunological relevance data for need of K1277/03 P90 strain in Pakistan as strain is locally not reported." EWG in its 9th meeting considered the data provided by the firm and decided to ask the firm to provide detailed studies of K1277/03 P90 strains regarding its similarity to existing strains of Pakistan.	
	Decision	
	Deferred	
	Keeping in view the recommendations of Expert Working Group on Veterinary Drugs; Registration board deferred the case for submission of detailed studies of K1277/03 P90 strain regarding its similarity to existing strains of Pakistan.	
45	Case Category	Routine (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 ^{6.5} EID50 Infectious bronchitis virus (IBV) CV 001 strain, CE4 (inactivated) --- minimum of 10 ^{6.5} EID50 Infectious bronchitis virus (IBV) CV013 strain, CE4 (inactivated) --- minimum of 10 ^{6.5} EID50 Duck adenovirus (Egg drop syndrome) (inactivated) minimum of 10 ⁸ EID50 Newcastle disease virus (NDV) LaSota strain (Inactivated) -- 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	
	Keeping in view the recommendations of EWG; Registration Board in its 352nd meeting deferred the case for submission of following by the firm: "Immunological relevance data for need of Infectious Bronchitis Virus (IBV CV 001 CE4 strain, IBV CV 0013 CE 4) as these strains are California and US variants." EWG in its 9th meeting considered the data provided by the firm and decided to ask the firm to provide detailed studies of Infectious Bronchitis Virus (IBV CV 001 CE4 strain, IBV CV 0013 CE 4) strains regarding their similarity to existing strains of Pakistan.	
	Decision	
	Deferred	
	Keeping in view the recommendations of Expert Working Group on Veterinary Drugs; Registration board deferred the case for submission of detailed studies of Infectious Bronchitis Virus (IBV CV 001 CE4 strain, IBV CV 0013 CE 4) strains regarding their similarity to existing strains of Pakistan.	
46	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	ALASAR 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	(1JW-R95-2B6R, 2024-12-26)
	Detail of Fee Submitted	300000.0, 2024-12-09,
	The proposed proprietary name / brand name	ValleyVac IBV3 - H9N2
	Label Claim	Each dose contains; A/chicken/Eg15106VL/2015(H9N2) HA antigen titer not less than 9 log2 IBV-Eg-15170F-SP1 strain antigen titer not less than 7.0 log10 EID50

		before inactivation IBV-P17-19 (ARK) strain antigen titer not less than 7.0 log10 EID50 before inactivation IBV-F734-HVR1-2-F (M41) strain antigen titer not less than 7.0 log10 EID50 before inactivation
	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)	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:	M/s Egyptian company for biological and pharmaceut-Block No. 101, 6th Industrial Zone, 6th of October City Giza, Egypt. -Egypt
	Name, address of Marketing Authorization Holder:	M/s Egyptian company for biological and pharmaceut, Block No. 101, 6th Industrial Zone, 6th of October City Giza, Egypt. , Egypt
	Details of Certificates (CoPP/FSC/cGMP):	FSC attached is not readable. Valid Legalized GMP has been provided.
	Details of Authorization Letter :	Not provided.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Not provided
	Evaluation Remarks	
	The Registration Board in its 347th meeting deferred the case due to following deficiencies in the application; 1. Evidence regarding immunological relevance of the strains applied & prevalence of disease in Pakistan is required. 2. Stability studies data, has not been provided. 3. Safety efficacy studies data has not been provided. 4. Notarized LOA from MAH, has not been provided. 5. The copy of FSC attached is not readable. 6. Multiple Pack sizes have been applied in single application. The Registration Board further directed the Division of BE&R to seek the opinion of M/o National Food Security & Research regarding immunological relevance and need of applied product in Pakistan. EWG in its 9th meeting considered the data provided by the firm and decided to ask the firm to provide detailed studies of applied strains regarding its similarity to existing strains of Pakistan. The firm has lab trials in safety and efficacy studies. The firm has requested to grant them pack as per DPC while this is a veterinary product.	
	Decision	
	Deferred	
	Keeping in view the recommendations of Expert Working Group on Veterinary Drugs; Registration board deferred the case for submission of following by the firm: 1. Detailed studies of applied strains regarding their similarity to existing strains of Pakistan. 2. Propose one pack as multiple pack are applied. 3. Safety and Efficacy data of field trials.	
47	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Inouko Animal Health (Private) Limited 3rd Floor, Plaza No. 3, D-Block, DHA Phase 5, Cantt, District Lahore (05-352-0058-043305D)
	Application Form Dy. No / Tracking ID & date of submission	(B3Z-1X2-J513, 2025-05-21)
	Detail of Fee Submitted	225000.0, 2025-03-18,

	The proposed proprietary name / brand name	Newflend ND H9
	Label Claim	One Dose vaccine contains: Cell-associated live recombinant Turkey herpesvirus (rHVT/ND-H9), expressing the fusion protein of Newcastle disease virus and the hemagglutinin H9-subtype of Low Pathogenic Avian Influenza min. 3000PFU*/Dose *PFU: plaque forming unit
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	2000 doses & 4000 do-De-Controlled
	Shelf Life (Unit)	24 MonthStore and transport Vaccine in liquid Nitrogen Container
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Ceva-Phylaxia Veterinary Biologicals Co.Ltd. -1107 Budapest, Szallas u. 5.,-Hungary
	Name, address of Marketing Authorization Holder:	Ceva-Phylaxia Veterinary Biologicals Co.Ltd., 1107 Budapest, Szallas u. 5.,, Hungary
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	The Registration Board in its 349th meeting referred the case to Expert Working Group on veterinary drugs for opinion regarding immunological relevance and need of applied product in Pakistan. The Board further advised DBE&R to ask the firm to submit the following: 1. The sole agency agreement has been signed by Seva Sante Animal Health S.A., France while the product license holder mentioned on the FSC is Ceva-Phylaxia Veterinary Biologicals Co.Ltd., Hungary. 2. The me-too product with the applied formulation is not already registered. The firm submitted the following: "The sole agency agreement has been signed by Ceva Santa Animal Health S.A. France because Ceva Phylaxia Veterinary Biologicals Co. Ltd., Hungary is the subsidiary of Ceva Santa Animal Health S.A. France. Bing a parent company and acting on behalf of its subsidiary company, sole agency agreement has been signed by Ceva Santa Animal Health S.A. France." EWG in its 9th meeting considered the data provided by the firm and decided to recommend the product for grant of registration.	
48	Decision	
	Approved	
	Keeping in view recommendation of Expert Working Group on Veterinary Drugs and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall select one pack size as multiple pack sizes are applied.	
	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Inouko Animal Health (Private) Limited 3rd Floor, Plaza No. 3, D-Block, DHA Phase 5, Cantt, District Lahore (05-352-0058-043305D)
	Application Form Dy. No / Tracking ID & date of submission	(D7W-7RG-LQV7, 2025-05-13)
	Detail of Fee Submitted	225000.0, 2025-03-18,
	The proposed proprietary name / brand name	Cevac Vitabron L
	Label Claim	One dose of Vaccine contains: New Castle Disease virus strain PHY.LMV.42.....at least 5.5

		log10 EID50 Avian infectious bronchitis virus strain H120.....at least 3.3 log10 EID50
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	2000 doses-De-Controlled
	Shelf Life (Unit)	18 Month(s)Store at 2-8 C, Protect from Light, don't freeze
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Veterinary Viral Vaccine
	Name, address of Manufacturing site:	Ceva-Phylaxia Veterinary Biologicals Co.Ltd. -1107 Budapest, Szallas u. 5.,-Hungary
	Name, address of Marketing Authorization Holder:	Ceva-Phylaxia Veterinary Biologicals Co.Ltd., 107 Budapest, Szallas u. 5.,, Hungary
	Details of Certificates (CoPP/FSC/cGMP):	Valid legalized FSC has been submitted. Valid legalized GMP certificate has been submitted.
	Details of Authorization Letter :	Sole agency agreement submitted is with Ceva Sante Animal S.A., France
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
	Evaluation Remarks	
	The Registration Board in its 349th meeting referred the case to Expert Working Group on veterinary drugs for the opinion regarding immunological relevance and need of applied product in Pakistan. The Board further advised DBE&R to ask the firm to submit the following: 1. The sole agency agreement has been signed by Seva Sante Animal Health S.A., France while the product license holder mentioned on the FSC is Ceva-Phylaxia Veterinary Biologicals Co. Ltd., Hungary. 2. The me-too product with New Castle Disease virus strain PHY.LMV.42 is not already registered. The firm submitted the following: 1. The sole agency agreement has been signed by Ceva Santa Animal Health S.A. France because Ceva Phylaxia Veterinary Biologicals Co. Ltd., Hungary is the subsidiary of Ceva Santa Animal Health S.A. France. Bing a parent company and acting on behalf of its subsidiary company, sole agency agreement has been signed by Ceva Santa Animal Health S.A. France. 2. The same strain is already registered in product Vitapest L Vaccine (Reg. No. 039909). EWG in its 9th meeting considered the data provided by the firm and decided to recommend the product for grant of registration.	
	Decision	
	Approved	
	Keeping in view recommendation of Expert Working Group on Veterinary Drugs and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
49	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	(QA3-6T7-PNEL, 2024-05-14)
	Detail of Fee Submitted	75000.0, 225000.0 2024-02-09, 2025-02-24
	The proposed proprietary name / brand name	RINVAC C RI
	Label Claim	RINVAC C RI Recombinant Canine α -Interferon, Freeze-dried - 2 Million IU/Vial. Solvent: Normal Saline
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Vials+1 Vial of 1-De-Controlled
	Shelf Life (Unit)	24 Month(s)2 - 8°C

	For generic drugs (me-too Status)	New Registration in Pakistan
	Pharmacotherapeutic Group of (API)	Veterinary Interferon
	Name, address of Manufacturing site:	Tianjin Ringpu Bio-Technology Co. Ltd.-Airport Economic Zone Branch, No. 168, Huanhe South Road, Airport Economic Zone, Tianjin-China
	Name, address of Marketing Authorization Holder:	Tianjin Ringpu Bio-Technology Co. Ltd., No. 1 Dongjiu Road, Tianjin Free Trade Area (Airport Economic Area), Tianjin, China
	Details of Certificates (CoPP/FSC/cGMP):	Valid legalized FSC & GMP certificate has been submitted.
	Details of Authorization Letter :	Legalized LOA form MAH has been submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
	Evaluation Remarks	
	Keeping in view the recommendations of EWG; Registration Board in its 352nd meeting deferred the case for submission of RRA status of formulation. The firm submitted their response which was considered in 9th meeting of EWG and EWG considered the data provided by the firm and decided to recommend the product for grant of registration.	
	Decision	
	Approved	
	Keeping in view recommendation of Expert Working Group on Veterinary Drugs and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
50	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Snam Pharma 61-G, Phase 1, Commercial Area, DHA, Lahore (05-352-0058-036985D)
	Application Form Dy. No / Tracking ID & date of submission	(WMN-4MW-WPZL, 2024-05-15)
	Detail of Fee Submitted	75000.0, 225000.0 2024-02-09, 2025-02-24
	The proposed proprietary name / brand name	RINVAC C RI
	Label Claim	RINVAC C RI Recombinant Canine α -Interferon, Freeze-dried - 5 Million IU/Vial
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Vials+1 Vial of 1-De-Controlled
	Shelf Life (Unit)	24 Month(s)2 - 8°C
	For generic drugs (me-too Status)	New Registration in Pakistan
	Pharmacotherapeutic Group of (API)	Veterinary Interferon
	Name, address of Manufacturing site:	Tianjin Ringpu Bio-Technology Co. Ltd.-Airport Economic Zone Branch, No. 168, Huanhe South Road, Airport Economic Zone, Tianjin-China
	Name, address of Marketing Authorization Holder:	Tianjin Ringpu Bio-Technology Co. Ltd., No. 1 Dongjiu Road, Tianjin Free Trade Area (Airport Economic Area), Tianjin, China
	Details of Certificates (CoPP/FSC/cGMP):	Valid legalized FSC & GMP certificate has been submitted.
	Details of Authorization Letter :	legalized LOA from MAH has been submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
	Evaluation Remarks	

	Registration Board in its 353^{re} meeting referred the case to Expert Working Group on Veterinary Drugs for their comments regarding firm's response on availability of formulation in RRAs. EWG in its 9th meeting considered the data provided by the firm and decided to recommend the product for grant of registration.	
	Decision	
	Approved	
	Keeping in view recommendation of Expert Working Group on Veterinary Drugs and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
51	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Medhouse Pharmaceuticals (PVT) Ltd. Mouza Mangowal Gharbi, 1 km off Chahmughlan Road, Tehsil & District Gujrat (09-342-0139-127900D)
	Application Form Dy. No / Tracking ID & date of submission	(YDM-AST-ZJXY, 2025-12-23)
	Detail of Fee Submitted	313500, 9400 2025-12-19, 2026-03-06
	The proposed proprietary name / brand name	HUIVAC DUO ND-H9
	Label Claim	The vaccine contains inactivated Newcastle disease virus strain La Sota , with a virus titer ≥ 108.0 EID ₅₀ /0.1ml before inactivation and inactivated avian influenza (H9 subtype) virus strain SZ, with virus titer ≥ 108.0 EID ₅₀ /0.1ml before inactivation.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500ml-De-Controlled
	Shelf Life (Unit)	18 Year(s)Store between 2C to 8C
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Luoyang Huizhong Biotech Co.,Ltd-No. 25, Yuwenkai Street, Luolong District, Luoyang City-China
	Name, address of Marketing Authorization Holder:	Luoyang Huizhong Biotech Co.,Ltd, No. 25, Yuwenkai Street, Luolong District, Luoyang City, China
	Details of Certificates (CoPP/FSC/cGMP):	.
	Details of Authorization Letter :	.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	EWG in its 9th meeting considered the data provided by the firm and decided to recommend the product for grant of registration.	
	Decision	
	Approved	
	Keeping in view recommendation of Expert Working Group on Veterinary Drugs and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
52	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Medhouse Pharmaceuticals (PVT) Ltd. Mouza Mangowal Gharbi, 1 km off Chahmughlan Road,

		Tehsil & District Gujrat (09-342-0139-127900D)
	Application Form Dy. No / Tracking ID & date of submission	(HVQ-R6B-Y84B, 2025-12-06)
	Detail of Fee Submitted	313500, 9400 2025-11-18, 2026-03-11
	The proposed proprietary name / brand name	HUIVAC BIVALENT (ND+H9)
	Label Claim	Each 0.1ml contains: Inactivated Newcastle disease virus, strain N7a..... $\geq 10^{8.6}$ EID ₅₀ before inactivation Inactivated Avian Influenza (H9 subtype) virus, strain SZ..... $\geq 10^{8.5}$ EID ₅₀ before inactivation
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500ml-De-Controlled
	Shelf Life (Unit)	18 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Luoyang Huizhong Biotech Co.,Ltd-No. 25, Yuwenkai Street, Luolong District, Luoyang City-China
	Name, address of Marketing Authorization Holder:	Luoyang Huizhong Biotech Co.,Ltd, No. 25, Yuwenkai Street, Luolong District, Luoyang City, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille GMP No. (2022) GMP 16015 dated 31-03-2022 valid till 30-03-2027. Scanned Apostille FSC dated 20-01-2026 valid till 02-12-2026.
	Details of Authorization Letter :	Scanned Apostille LOA dated 26-01-2026.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A.
	Evaluation Remarks	
	EWG in its 9th meeting considered the data provided by the firm and decided to ask the firm to provide detailed studies of N7a strain regarding its similarity to existing strains of Pakistan.	
	Decision	
	Deferred	
	Keeping in view the recommendations of Expert Working Group on Veterinary Drugs; Registration board deferred the case for submission of detailed studies of N7a strain regarding its similarity to existing strains of Pakistan.	
53	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Hilton Pharma (Pvt.) Limited Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area Karachi, Pakistan (0647.)
	Application Form Dy. No / Tracking ID & date of submission	(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 $10^{7.0}$EID₅₀ Inactivated Adenovirus 127 virus, Mc Ferran strain.....at least 1000 HA unit - Inactivated Infectious Bronchitis (IB) virus of Massachusetts 41.....at least $10^{4.5}$EID₅₀ Inactivated Infectious Bronchitis (IB) virus of (M01 strain (M01 strain identical to Genotype G1-19 or QX-like group).....at least $10^{4.5}$EID₅₀ Inactivated Infectious Bronchitis (IB) virus of M02 strain (M02 strain identical to Genotype G1-13 or 793B group).....at least $10^{4.5}$EID₅₀
	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, Jl. Babakan Ciparay No.282, Babakan Ciparay, Bandung, Indonesia
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	Scanned Apostille copy of distribution agreement dated 01-02-2005 with updated product list dated 31-10-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	EWG in its 9th meeting considered the data provided by the firm and decided to ask the firm to provide more detailed studies of MD54, M01 & M02 strains regarding their similarity to existing strains of Pakistan.	
	Decision	
	Deferred	
	Keeping in view the recommendations of Expert Working Group on Veterinary Drugs; Registration board deferred the case for submission of detailed studies of MD54, M01 & M02 strains regarding their similarity to existing strains of Pakistan.	
54	Case Category	Routine (M. Zubair Masood)
	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	(NBU-WMN-RMTD, 2026-04-20)
Detail of Fee Submitted	300000.0, 13500 2025-07-28, 2025-08-29
The proposed proprietary name / brand name	Glargem-300 Solution for Injection
Label Claim	Each 3mL Contains: Recombinant Insulin Glargine..... 300 IU (3mL Cartridge) USP Specifications
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's (3mL Cartridge)-As per SRO
Shelf Life (Unit)	3 YearsStore below 2°C to 8°C in a refrigerator. Do not freeze.
For generic drugs (me-too Status)	Lantus Optiset Injection 300Units/3mL by Sanofi Aventis Pakistan Limited, Karachi
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Fosun Wanbang (Jiangsu) Pharmaceutical Group Co., -South of Dongshan, Comprehensive Area, Jinshanqiao Development Zone, Xuzhou, Jiangsu, China -China
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Fosun Wanbang (Jiangsu) Pharmaceutical Group Co., , South of Dongshan, Comprehensive Area, Jinshanqiao Development Zone, Xuzhou, Jiangsu , 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	Lantus Solostar Injection 300Units/3mL by Sanofi Aventis US

Evaluation Remarks

Initially, the firm applied for registration on their DML instead of DSL. Both are different entities. Fee was also submitted by DML holder instead of DSL holder. Later on, MIS Division on the request of the firm transferred the application to the account of DSL. However, the DSL Holder has not submitted the fee and submitted the following: "The fee has already been deposited and verified through the DRAP portal. It is requested that the same be adjusted,as re-payment of the fee is not feasible from our end." Four rounds of communication has already been done with the firm and following are still the shortcomings: 1. Apostille/ Legalized CoPP is required. 2. Characterization studies of applied product are not in comparison with Innovator product while these are required as per guidelines. 3. The firm has provided details of products in same Section. There are two production lines Line 2 & Line 3. On line 3, the products manufactured are Biological products, while on line 2, one of the products manufactured i.e. Meglumine Adenosine Cyclophosphate Injection is a pharmaceutical product. 4. Evidence of approval of 24 months shelf life from country of origin as initially, the proposed shelf life in E-App was 3 years while firm mentioned 24 months shelf life in dossier.

Decision

Deferred

Registration Board deferred the case for following:

1. Fee adjustment to DSL account by the firm.
2. Submission of Apostille/ Legalized CoPP.

	3. Detailed Characterization studies of applied product in comparison with Innovator product.	
	4. Clarification of manufacturing of Meglumine Adenosine Cyclophosphate Injection a pharmaceutical product on Line 2 along with other rDNA Insulins.	
	5. Submission of evidence of approval of 24 months shelf life from country of origin.	
55	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	(J6E-HMG-X1TH, 2026-04-20)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	Meritus 300IU Injection
	Label Claim	Each Pre-filled pen (3ml) contains: Insulin Glargine.....300IU
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store between 2°C to 8°C
	For generic drugs (me-too Status)	BASAGINE (GETZ PHRMA)
	Pharmacotherapeutic Group of (API)	Long-acting basal insulin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Tonghua Dongbao Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Three Batches: 102D01, 102D02, 102D03 Size: 300, 200 & 200 Cartridges Conditions: 2-8C Frequency: 0,3,6 months Accelerated & 0,3,6, months Real Time
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not Provided.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: AG20231100244, AG20231100254, AG20231100264 Conditions: -20C Frequency: 0,1,2,3,6 moths Accelerated & 0,3,6,9,12,18 & 24 months Real Time
	The status in reference regulatory authorities	LANTUS 300 IU/3mL Injection USFDA APPROVED
	GMP status of the firm	The firm has got Section approval on 24-03-2026.
	Evidence of approval of manufacturing facility	The firm has got Section approval on 24-03-2026.
Evaluation Remarks		
Following were the observations: 1. The clearance provided by you is of batch AL2025040018 while COAs provided in Module-3 performed by local manufacturer are of three batches i.e. AG20250300014, AG20250300024 & AG20250300034. Please explain? 2. The provided CoPP is of Insulin Glargine API while you were advised to submit Evidence of approval of finished product manufactured from same API in country of origin? The firm provided the following response: 1. We are writing to formally clarify a clerical error made during the data entry process in the Pakistan Single Window (PSW) system regarding our recent import of Insulin Glargine. Due to an inadvertent typographical error, our clearing agent entered an incorrect reference number (AL2025040018) in the Certificate of Analysis (CoA) field. 2. The firm has submitted a CoPP of Insulin Glargine Injection which is neither legalized/ Apostille nor can be verified from official NMPA database. Moreover, the strength or composition are also not mentioned on the CoPP.		
Decision		

	Approved	
	Registration Board approved the product subject to submission of online verifiable CoPP of product manufactured from same Drug substance in China and product specific inspection of local manufacturer.	
56	Case Category	Routine (Muneeb Ahmed Cheema)
	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	(U68-DNN-35UM, 2026-01-30)
	Detail of Fee Submitted	313500, 2026-01-28,
	The proposed proprietary name / brand name	ORNIVAC FC Emulsion for injection
	Label Claim	ORNIVAC FC Emulsion for Injection Inactivated vaccine against bacterial poultry pasteurellosis caused by Pasteurella Multocida serotypes A1, A3, A4, A3&4. Each dose (0.5 ml) contains: Pasteurella multocida, serotype A1, strain X-73, inactivated: RP ≥ 1*, Pasteurella multocida, serotype A3, strain P-1059, inactivated: RP ≥ 1*, Pasteurella multocida, serotype A4, strain P-1662, inactivated: RP ≥ 1*, Pasteurella multocida, serotype A3x4, strain CU, inactivated: RP ≥ 1*
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1 x 500 ml (1000 doses)-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store at 2°C - 8°C
	For generic drugs (me-too Status)	Same Formulation already registered in Pakistan
	Pharmacotherapeutic Group of (API)	Poultry Vaccine (Bacterial Pasteurellosis)
	Name, address of Manufacturing site:	Bioveta, a.s.-Komenskeho 212, 683 23 Ivanovice na Hane-Czechia (Czech Republic)
	Name, address of Marketing Authorization Holder:	Bioveta, a.s., Komenskeho 212, 683 23 Ivanovice na Hane, Czechia (Czech Republic)
	Details of Certificates (CoPP/FSC/cGMP):	Firm has submitted the Legalized certificate of GMP Compliance issued by Regulatory Authority of Czech Republic Dated 06.0.2025
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	NA
	Evaluation Remarks	
	The submitted CoPP is not legalized	
	Decision	
	Approved	
	Keeping in view CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of valid legalized/ Apostille CoPP.	
57	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	QAS INTERNATIONAL PLOT # 153/155, MUSTAFA ABAD TEHSIL KAMOKE (09-341-0134-103105D)
	Application Form Dy. No / Tracking ID & date of submission	(A8L-JPS-97NT, 2025-07-04)

Detail of Fee Submitted	300000.0, 9400.0 2025-07-02, 2025-08-27	
The proposed proprietary name / brand name	ANIVAC FAdV 5	
Label Claim	Fowl Adenovirus (FAdV) Serotype 2, 4, 8a, 8b and 11 Fowl Adenovirus Serotype 2 > 1x106.5 TCID50 Fowl Adenovirus Serotype 4 > 1x106.5 TCID50 Fowl Adenovirus Serotype 8a > 1x106.5 TCID50 Fowl Adenovirus Serotype 8b > 1x106.5 TCID50 Fowl Adenovirus Serotype 11 > 1x106.5 TCID50	
Reference to Finished product specifications	European Pharmacopeia	
Proposed Pack Size	500ml/1000 doses-De-Controlled	
Shelf Life (Unit)	12 MonthStore at 2 ~ 8°C	
For generic drugs (me-too Status)	ANIVAC FAdV 5	
Pharmacotherapeutic Group of (API)		
Name, address of Manufacturing site:	SAN Group Biotech Germany GmbH- Muehlenstraße 13 49685 Hoeltinghausen Germany-Germany	
Name, address of Marketing Authorization Holder:	SAN Group Biotech Germany GmbH, Muehlenster 13, 49685 Hoeltinghuasen,, Germany	
Details of Certificates (CoPP/FSC/cGMP):		
Details of Authorization Letter :		
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		
Evaluation Remarks		
An autogenous (or herd-autogenous) vaccine is a bacterin/toxoid/viral preparation made from pathogens isolated from the same herd, flock or client population and returned to that herd (or a defined group) to help control a disease when no suitable licensed vaccine exists. Autogenous are not a first-line intervention but are indispensable for controlling specific, persistent infectious diseases caused by pathogens with significant strain variation or for which no commercial alternative exists. The application has already been reviewed, and the deficiencies/ shortcomings were communicated to the applicant. However, the applicant has not yet submitted response which pending since August 29, 2025 for ANIVAC FAdV 5. Moreover, the matter of Autogenous vaccines was referred to M/s National Food Security and their response is as under: "The disease burden in Pakistan indicates a genuine clinical need for effective vaccines against MG/MS and FAdV; however, the specific autogenous products under review cannot be supported in their present form. These vaccines are neither licensed in the country of origin nor accompanied by essential safety, efficacy, or strain-matching data. Approving such unverified products would entail regulatory and biosafety risks. Therefore, the Registration Board may not support approval at this stage and may advise the applicant to submit complete safety and efficacy data, including controlled field-trial results, along with antigenic-similarity evidence demonstrating alignment with Pakistani field isolates. Only upon fulfilment of these fundamental requirements may the applications be processed further." Keeping in view the recommendations of Ministry of National Food Security & Research; Registration Board deferred the product for submission of following by the firm in its 353rd meeting the response of firm is as under:		
Sr. No.	Query (M-353)	Response
1.	Complete safety and efficacy data including controlled field-trial results	Clinical report for a killed Adenovirus (FAdV) polyvalent vaccine evaluated at Sanabai Agri & Poultry Company (SAPCO), Yemen in breeder and layer flocks over 12 months. The document contains real time data for the use of ANNIVAC FAdV with serotype 2, 4, 8a, 8b & 11. The study concluded that the killed Adenovirus vaccine provides substantial protection in breeder and layer flocks, with

		reduced mortality, higher seroconversion, and improved production metrics. Safety profile is acceptable.
2.	Antigenic-similarity evidence demonstrating alignment with Pakistani field isolates.	The applicant submitted merely statement that the strains of Fowl Adenovirus (FAdV) Serotype 2, 4, 8a, 8b and 11 are the same as used for Vaccines registered in Yemen that have been identified by sending the isolates from Pakistan.
3.	Free Sale Certificate indicating quantitative composition issued by regulatory authority of country of origin instead of issued by the firm.	The firm submitted a Freescale Certificate issued by SAN Group Germany (Manufacturer) which states that they are authorized to produce autogenous vaccines including the ANIVAC FAdV5 Vaccine. Moreover, a Freesale Certificate issued by Directorate General of Animal Health and Veterinary Quarantine, Ministry of Agriculture & Fisheries & Water Resources Yemen, which indicates that ANIVAC FAdV5 Poultry vaccine (500ml/1000 dose) is produce by San Group Biotech Germany are registered and freely sold in Yemen.
4.	Clarification of submitted Contract Agreement as the supplier is M/s San Vet Holding GmbH, Austria while GMP submitted is of M/s San Group Biotech Germany GmbH, Germany?	Letter of Authorization has been submitted by SAN Group Austria which mentions that SAN Group Biotech Germany GmbH with address at
5.	Fee of Rs. 9400/- along with details of foreign MAH.	The applicant has submitted the required fee.
6.	Scanned legalized/ Apostille GMP certificate issued by Regulatory Authority of Germany.	Legalized GMP certificate issued by the regulatory authority of country of origin is submitted which indicates that the manufacturer M/s SAN Group Biotech Germany GmbH Muhlenstrabe 13, D-49685 Holtinghausen Deutschland Germany holds manufacturing authorization for autogenous vaccines.
7.	Clarification of monograph to be used for testing of product or In-house specs	The firm has submitted the Quality documentation which includes finished product specification and analytical procedures.
8.	Clarification of address at which the product shall be stored.	As per submitted DSL, the applicant address is as under: M/S QAS International, Plot No.153/155 Mustafa Abad Tehsil Kamoke Gujranwala Pakistan and Godown address is Opposite Grace Marquee Near Subhan Ceramics Main G.T Road Gujranwala District: Gujranwala. The applicant has attached Cold storage verification report of DRAP Lahore for their cold storage facility at Opposite Grace Marquee Near Subhan Ceramics Main G.T Road Gujranwala District: Gujranwala.
9.	Clarification of not performing assay test during stability studies.	The assay (antigen titre) s a critical in-process control parameter performed prior to inactivation to ensure consistency, quality and uniformity of the antigen during manufacturing. This control ensures that each batch meets the validated specifications before further processing. For the finished inactivated vaccine product, stability studies are designed to monitor parameters that are stability-indicating, such as sterility safety, and other relevant quality attributes. These parameters are considered sufficient to demonstrate product stability over the proposed shelf life. Scientifically, it is established that once the antigen is inactivated and formulated, the antigen content remains stable under

		recommended storage conditions. This is supported by process validation and consistency of batch manufacturing data. Therefore, routine assay testing during stability studies has not been included, as the assay is controlled at the manufacturing stage and does not significantly vary during storage. Conclusion: Based on manufacturing controls, process validation, and batch consistency, the antigen content remains within validated limits, and the omission of assay testing during stability studies is scientifically justified.
Decision		
Deferred		
Registration Board referred the case to Expert Working Group on Veterinary Drugs for their opinion regarding safety, efficacy data submitted by the firm and antigenic similarity of applied product with Pakistani field isolate as recommended by M/s NFS&R.		
58	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	QAS INTERNATIONAL PLOT # 153/155, MUSTAFA ABAD TEHSIL KAMOKE (09-341-0134-103105D)
	Application Form Dy. No / Tracking ID & date of submission	(1NN-RD7-YZJP, 2025-07-25)
	Detail of Fee Submitted	300000.0, 9400 2025-07-22, 2026-02-17
	The proposed proprietary name / brand name	ANIVAC Mg, Ms
	Label Claim	Active substances Quantity per dose (0.5 ml) Mycoplasma gallisepticum > 1x10 ⁷ CFU Mycoplasma synoviae > 1x10 ⁷ CFU
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	500ml/1000 doses-De-Controlled
	Shelf Life (Unit)	12 MonthStore at 2 ~ 8°C
	For generic drugs (me-too Status)	ANIVAC Mg, Ms
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SAN Group Biotech Germany GmbH- Muehlenstr. 13 49685 Hoeltinghausen GERMANY-Germany
	Name, address of Marketing Authorization Holder:	Ahmed Saleem Goriya, Plot # 153/155, Mustafa Abad, Tehsil Kamoki, District Gujranwala, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
Evaluation Remarks		
Recommendation of NFSR: An autogenous (or herd-autogenous) vaccine is a bacterin/toxoid/viral preparation made from pathogens isolated from the same herd, flock or client population and returned to that herd (or a defined group) to help control a disease when no suitable licensed vaccine exists. Autogenous are not a first-line intervention but are indispensable for controlling specific, persistent infectious diseases caused by pathogens with significant strain variation or for which no commercial alternative exists. The application has already been reviewed, and the deficiencies/ shortcomings were communicated to the applicant. However, the applicant has not yet submitted response which pending since September 11, 2025 for ANIVAC Mg, Ms. Moreover, the matter of Autogenous vaccines was referred to M/s National Food Security and their response is as under: "The disease burden in Pakistan indicates a genuine clinical need for effective vaccines against		

MG/MS and FAdV; however, the specific autogenous products under review cannot be supported in their present form. These vaccines are neither licensed in the country of origin nor accompanied by essential safety, efficacy, or strain-matching data. Approving such unverified products would entail regulatory and biosafety risks. Therefore, the Registration Board may not support approval at this stage and may advise the applicant to submit complete safety and efficacy data, including controlled field-trial results, along with antigenic-similarity evidence demonstrating alignment with Pakistani field isolates. Only upon fulfilment of these fundamental requirements may the applications be processed further." Keeping in view the recommendations of Ministry of National Food Security & Research; Registration Board deferred the product for submission of following by the firm in its 353rd meeting. Response of the firm is as under:

Sr. No.	Query (M-353)	Response
1.	Complete safety and efficacy data including controlled field-trial results	The firm has attached the Field Efficacy & Safety Evaluation of Inactivated MG + MS Vaccine conducted at Sanabai Agri & Poultry (SAPCO), Yemen for Breeders & Layers for 16 Weeks (4 Months). Clinical Interpretation of the study is as under: The inactivated MG + MS vaccine demonstrated a strong immune response, reflected in high ELISA GMT values for both MG and MS in vaccinated flocks compared to controls ($p < 0.001$). Mortality and clinical disease incidence (CRD, synovitis) were significantly lower in vaccinated birds. Performance indicators such as FCR, weight gain (breeders), and egg production (layers) also showed statistically significant improvements in vaccinated flocks. Body temperature remained within normal physiological range across both groups, with only mild transient reactions noted post-vaccination. No serious adverse events were observed, and overall tolerability was high.
2.	Antigenic-similarity evidence demonstrating alignment with Pakistani field isolates.	The applicant submitted merely statement that the strains of Mg,Ms i.e., R-Strain, S-Strain and Field Strain are the same as used for Vaccines registered in Yemen that have been identified by sending the isolates from Pakistan.
3.	Free Sale Certificate indicating quantitative composition issued by regulatory authority of country of origin instead of issued by the firm.	The firm submitted a Freescale Certificate issued by SAN Group Germany (Manufacturer) which states that they are authorized to produce autogenous vaccines including the ANIVAC Mg, Ms Vaccine. Moreover, a Freesale Certificate issued by Directorate General of Animal Health and Veterinary Quarantine, Ministry of Agriculture & Fisheries & Water Resources Yemen, which indicates that ANIVAC Mg, Ms Poultry vaccine (500ml/1000 dose) is produce by San Group Biotech Germany are registered and freely sold in Yemen.
4.	Clarification of submitted Contract Agreement as the supplier is M/s San Vet Holding GmbH, Austria while GMP submitted is of M/s San Group Biotech Germany GmbH, Germany?	Letter of Authorization has been submitted by SAN Group Austria which mentions that SAN Group Biotech Germany GmbH with address at
5.	Fee of Rs. 9400/- along with details of foreign MAH.	The applicant has submitted the required fee.
6.	Scanned legalized/ Apostille GMP certificate issued by Regulatory Authority of Germany.	Legalized GMP certificate issued by the regulatory authority of country of origin is submitted which indicates that the manufacturer M/s SAN Group Biotech Germany GmbH Muhlenstrabe 13, D-49685 Holtinghausen Deutschland Germany holds manufacturing authorization for autogenous vaccines.

7.	Clarification of monograph to be used for testing of product or In-house specs	The firm has submitted the Quality documentation which includes finished product specification and analytical procedures.
8.	Clarification of address at which the product shall be stored.	As per submitted DSL, the applicant address is as under: M/S QAS International, Plot No.153/155 Mustafa Abad Tehsil Kamoke Gujranwala Pakistan and Godown address is Opposite Grace Marquee Near Subhan Ceramics Main G.T Road Gujranwala District: Gujranwala. The applicant has attached Cold storage verification report of DRAP Lahore for their cold storage facility at Opposite Grace Marquee Near Subhan Ceramics Main G.T Road Gujranwala District: Gujranwala.
9.	Clarification of not performing assay test during stability studies.	The assay (antigen titre) is a critical in-process control parameter performed prior to inactivation to ensure consistency, quality and uniformity of the antigen during manufacturing. This control ensures that each batch meets the validated specifications before further processing. For the finished inactivated vaccine product, stability studies are designed to monitor parameters that are stability-indicating, such as sterility safety, and other relevant quality attributes. These parameters are considered sufficient to demonstrate product stability over the proposed shelf life. Scientifically, it is established that once the antigen is inactivated and formulated, the antigen content remains stable under recommended storage conditions. This is supported by process validation and consistency of batch manufacturing data. Therefore, routine assay testing during stability studies has not been included, as the assay is controlled at the manufacturing stage and does not significantly vary during storage. Conclusion: Based on manufacturing controls, process validation, and batch consistency, the antigen content remains within validated limits, and the omission of assay testing during stability studies is scientifically justified.

Decision

Deferred

Registration Board referred the case to Expert Working Group on Veterinary Drugs for their opinion regarding safety, efficacy data submitted by the firm and antigenic similarity of applied product with Pakistani field isolates as recommended by M/s NFS&R.

59	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	CCL Pharmaceuticals Pvt. Ltd. Plot No. 710 Sundar Industrial Estate, Raiwind Road Lahore (05-352-0066-126587D)
	Application Form Dy. No / Tracking ID & date of submission	(JT6-AHL-L99A, 2026-01-08)
	Detail of Fee Submitted	313500, 2025-12-10,
	The proposed proprietary name / brand name	Sejaro
	Label Claim	Each 0.6ml contains: Tirzepatide.....7.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 5±3 °C
	For generic drugs (me-too Status)	Zepatide-Macter International

Pharmacotherapeutic Group of (API)	GLP and GIP Receptor Agonist: Drugs used in diabetes, blood glucose lowering drugs, excl. insulins, ATC code: A10BX16
Name, address of Manufacturing site:	GEROPHARM-Bldg. 5, Kvartal A area, Obolensk settlement, Serpukhov city, district, Moscow region-Russia
Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analytical characterization is provided with Innovator
Name, address of Marketing Authorization Holder:	CCL Pharmaceuticals (Pvt.) Ltd., Plot No. 710, Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	CoPP issued by Russian Authorities provides the GMP status
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 12 months real time, stability data of 3 pilot scale batches available. Stability data of batch No. ZG27230701 manufactured in August 2023 is not available
The status in reference regulatory authorities	Mounjaro-FDA

Evaluation Remarks

Registration Board in its 354 th meeting deferred for following: justification by the manufacturer regarding the quantity of API imported from M/s Zhejiang Peptides Biotech Co., Ltd., China for manufacturing of their pilot and commercial scale batches submitted in the dossier. Stability data of batches used in manufacturing pilot and commercial scale batches of product. The response of the firm is as below: API quantity of about 500grams (batch Number ZG27230701) was imported from M/s Zhejiang Peptides Biotech Co., Ltd., China for manufacturing of drug product stability batches submitted in the Reconciliation of API quantity used is tabulated below:

Pilot batches					
Product Name	strength	1st Batch Size	2nd Batch Size	3rd Batch Size	API used (gram)
Sejaro, solution for subcutaneous injection	2.5mg/dose	656	659	657	19.72
	5mg/dose	640	646	655	38.82
	7.5mg/dose	649	652	651	58.56
	10mg/dose	656	659	657	78.88
	12.5mg/dose	640	646	655	97.05
	15mg/dose	649	652	651	117.12
	Total				410.15

The batches referred to as “pilot batches” in the dossier were manufactured at a scale representative of the proposed commercial batch size and strictly in accordance with current Good Manufacturing Practices (cGMP). They were initially designated as pilot batches for the purpose of their use in the validation and stability studies, else while the size, processing parameters and conditions were same as that of commercial batch. These batches were produced using: The same qualitative and quantitative composition as the proposed commercial formulation. Identical manufacturing process and controls as described in the dossier. Qualified equipment and manufacturing facility compliant with GMP requirements. Validated analytical methods and approved specifications. The batches referred to as “pilot batches” in the dossier were manufactured at a scale representative of the proposed commercial batch size and strictly in accordance with current Good Manufacturing Practices (cGMP). They were initially designated as pilot batches for the purpose of their use in the validation and stability studies, else while the size, processing parameters and conditions were same as that of commercial batch. These batches were produced using: The same qualitative and quantitative composition as the propose commercial Identical manufacturing process and controls as described in the Qualified equipment and manufacturing facility compliant with GMP Validated analytical methods and approved The manufacturing process had already reached a state of consistency and reproducibility at the time of production of these batches. Complete batch manufacturing records and quality control documentation, reflecting the batch size and other

processing parameters are available. Annex-1 Stability studies (accelerated and long-term) have been performed on these batches in accordance with ICH guidelines, and the available data supports the proposed shelf The Active Pharmaceutical Ingredient (API) used in our product has been procured from M/s Zhejiang Peptides Biotech Co., Ltd., China, which is a well- recognized and previously evaluated manufacturer. The firm further mention that during the 352nd Meeting of the Registration Board of DRAP, a case involving API sourced from M/s Zhejiang Peptides Biotech Co., Ltd., China was reviewed and approved by the honorable Board. This reflects that the said manufacturer has undergone prior regulatory evaluation and was found acceptable with respect to quality, compliance, and stability for pharmaceutical use.

Decision

Deferred

The Registration Board decided to grant the firm an opportunity for a personal hearing to justify their response of decision of 354th meeting of Registration Board submitted on 14-04-2026.

60	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	CCL Pharmaceuticals Pvt. Ltd. Plot No. 710 Sundar Industrial Estate, Raiwind Road Lahore (05-352-0066-126587D)
	Application Form Dy. No / Tracking ID & date of submission	(UB8-EW5-6GP4, 2026-01-08)
	Detail of Fee Submitted	313500, 2025-12-10,
	The proposed proprietary name / brand name	Sejaro
	Label Claim	Each 0.6ml contains: Tirzepatide.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 5±3 °C
	For generic drugs (me-too Status)	Zepatide-Macter International
	Pharmacotherapeutic Group of (API)	GLP and GIP Receptor Agonist: Drugs used in diabetes, blood glucose lowering drugs, excl. insulins, ATC code: A10BX16
	Name, address of Manufacturing site:	GEROPHARM-Bldg. 5, Kvartal A area, Obolensk settlement, Serpukhov city district, Moscow region-Russia
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analytical characterization is provided with Innovator
	Name, address of Marketing Authorization Holder:	CCL Pharmaceuticals (Pvt.) Ltd., Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	CoPP submitted indicates the GMP of manufacturer
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 12 months real time, stability data of 3 pilot scale batches available. Stability data of batch No. ZG27230701 manufactured in August 2023 is not available.
	The status in reference regulatory authorities	Mounjaro-FDA

Evaluation Remarks

Registration Board in its 354 th meeting deferred for following: justification by the manufacturer regarding the quantity of API imported from M/s Zhejiang Peptides Biotech Co., Ltd., China for manufacturing of their pilot and commercial scale batches submitted in the dossier. Stability data of batches used in manufacturing pilot and commercial scale batches of product. The response of the firm is as below: API quantity of about 500grams (batch Number ZG27230701) was imported from

M/s Zhejiang Peptides Biotech Co., Ltd., China for manufacturing of drug product stability batches submitted in the Reconciliation of API quantity used is tabulated below:

Pilot batches					
Product Name	strength	1st Batch Size	2nd Batch Size	3rd Batch Size	API used (gram)
Sejaro, solution for subcutaneous injection	2.5mg/dose	656	659	657	19.72
	5mg/dose	640	646	655	38.82
	7.5mg/dose	649	652	651	58.56
	10mg/dose	656	659	657	78.88
	12.5mg/dose	640	646	655	97.05
	15mg/dose	649	652	651	117.12
	Total				410.15

The batches referred to as “pilot batches” in the dossier were manufactured at a scale representative of the proposed commercial batch size and strictly in accordance with current Good Manufacturing Practices (cGMP). They were initially designated as pilot batches for the purpose of their use in the validation and stability studies, else while the size, processing parameters and conditions were same as that of commercial batch. These batches were produced using: The same qualitative and quantitative composition as the proposed commercial formulation. Identical manufacturing process and controls as described in the dossier. Qualified equipment and manufacturing facility compliant with GMP requirements. Validated analytical methods and approved specifications. The batches referred to as “pilot batches” in the dossier were manufactured at a scale representative of the proposed commercial batch size and strictly in accordance with current Good Manufacturing Practices (cGMP). They were initially designated as pilot batches for the purpose of their use in the validation and stability studies, else while the size, processing parameters and conditions were same as that of commercial batch. These batches were produced using: The same qualitative and quantitative composition as the propose commercial Identical manufacturing process and controls as described in the Qualified equipment and manufacturing facility compliant with GMP Validated analytical methods and approved The manufacturing process had already reached a state of consistency and reproducibility at the time of production of these batches. Complete batch manufacturing records and quality control documentation, reflecting the batch size and other processing parameters are available. Annex-1 Stability studies (accelerated and long-term) have been performed on these batches in accordance with ICH guidelines, and the available data supports the proposed shelf The Active Pharmaceutical Ingredient (API) used in our product has been procured from M/s Zhejiang Peptides Biotech Co., Ltd., China, which is a well- recognized and previously evaluated manufacturer. The firm further mention that during the 352nd Meeting of the Registration Board of DRAP, a case involving API sourced from M/s Zhejiang Peptides Biotech Co., Ltd., China was reviewed and approved by the honorable Board. This reflects that the said manufacturer has undergone prior regulatory evaluation and was found acceptable with respect to quality, compliance, and stability for pharmaceutical use.

Decision

Deferred

The Registration Board decided to grant the firm an opportunity for a personal hearing to justify their response of decision of 354th meeting of Registration Board submitted on 14-04-2026.

61	Case Category	Routine (Muneeb Ahmed Cheema)
	Name, address of Applicant.	CCL Pharmaceuticals Pvt. Ltd. Plot No. 710 Sundar Industrial Estate, Raiwind Road Lahore (05-352-0066-126587D)
	Application Form Dy. No / Tracking ID & date of submission	(VW9-TGH-MJTM, 2026-01-08)
	Detail of Fee Submitted	313500, 2025-12-10,
	The proposed proprietary name / brand name	Sejaro
	Label Claim	Each 0.6ml contains: Tirzepatde.....5mg

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at 5±3 °C
For generic drugs (me-too Status)	Zepatide-Macter International
Pharmacotherapeutic Group of (API)	GLP and GIP Receptor Agonist: Drugs used in diabetes, blood glucose lowering drugs, excl. insulins, ATC code: A10BX16
Name, address of Manufacturing site:	GEROPHARM-Bldg. 5, Kvartal A area, Obolensk settlement, Serpukhov city, district, Moscow region-Russia
Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analytical characterization is provided with Innovator
Name, address of Marketing Authorization Holder:	CCL Pharmaceuticals (Pvt.) Ltd., Plot No. 710, Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	CoPP indicates GMP of manufacturer
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 12 months real time, stability data of 3 pilot scale batches available. Stability data of batch No. ZG27230701 manufactured in August 2023 is not available.
The status in reference regulatory authorities	Mounjaro-FDA

Evaluation Remarks

Registration Board in its 354 meeting deferred for following: justification by the manufacturer regarding the quantity of API imported from M/s Zhejiang Peptides Biotech Co., Ltd., China for manufacturing of their pilot and commercial scale batches submitted in the dossier. Stability data of batches used in manufacturing pilot and commercial scale batches of product. The response of the firm is as below: API quantity of about 500grams (batch Number ZG27230701) was imported from M/s Zhejiang Peptides Biotech Co., Ltd., China for manufacturing of drug product stability batches submitted in the Reconciliation of API quantity used is tabulated below:

Pilot batches					
Product Name	strength	1st Batch Size	2nd Batch Size	3rd Batch Size	API used (gram)
Sejaro, solution for subcutaneous injection	2.5mg/dose	656	659	657	19.72
	5mg/dose	640	646	655	38.82
	7.5mg/dose	649	652	651	58.56
	10mg/dose	656	659	657	78.88
	12.5mg/dose	640	646	655	97.05
	15mg/dose	649	652	651	117.12
	Total				410.15

The batches referred to as “pilot batches” in the dossier were manufactured at a scale representative of the proposed commercial batch size and strictly in accordance with current Good Manufacturing Practices (cGMP). They were initially designated as pilot batches for the purpose of their use in the validation and stability studies, else while the size, processing parameters and conditions were same as that of commercial batch. These batches were produced using: The same qualitative and quantitative composition as the proposed commercial formulation. Identical manufacturing process and controls as described in the dossier. Qualified equipment and manufacturing facility compliant with GMP requirements. Validated analytical methods and approved specifications. The batches referred to as “pilot batches” in the dossier were manufactured at a scale representative of the proposed commercial batch size and strictly in accordance with current Good Manufacturing Practices (cGMP). They were initially designated as pilot batches for the purpose of their use in the validation and stability studies, else while the size, processing parameters and conditions were same as that of commercial batch. These batches were produced using: The same qualitative and quantitative composition as the propose commercial Identical manufacturing process and controls as

described in the Qualified equipment and manufacturing facility compliant with GMP Validated analytical methods and approved The manufacturing process had already reached a state of consistency and reproducibility at the time of production of these batches. Complete batch manufacturing records and quality control documentation, reflecting the batch size and other processing parameters are available. Annex-1 Stability studies (accelerated and long-term) have been performed on these batches in accordance with ICH guidelines, and the available data supports the proposed shelf The Active Pharmaceutical Ingredient (API) used in our product has been procured from M/s Zhejiang Peptides Biotech Co., Ltd., China, which is a well- recognized and previously evaluated manufacturer. The firm further mention that during the 352nd Meeting of the Registration Board of DRAP, a case involving API sourced from M/s Zhejiang Peptides Biotech Co., Ltd., China was reviewed and approved by the honorable Board. This reflects that the said manufacturer has undergone prior regulatory evaluation and was found acceptable with respect to quality, compliance, and stability for pharmaceutical use.

Decision

Deferred

The Registration Board decided to grant the firm an opportunity for a personal hearing to justify their response of decision of 354th meeting of Registration Board submitted on 14-04-2026.

Case No: 1 Application for registration of Buccalin Tablets applied by M/s RG Pharmaceutica (Pvt.) Ltd., 247-Sundar Industrial State, Lahore.

Registration Board in its 282nd meetings approved the following biological product of M/s RG Pharmaceutica Pvt. Ltd., Progressive Square No. 703, Block-6 PECHS, Shahra e Faisal, Karachi. The details are as under:

Sr. No.	Brand name and composition	Name of manufacturer/ product license holder	Packing and shelf life
1.	BUCCALIN (Gastroresistant Tablets for Adults & Children) Each tablet contains: <i>Streptococcus pneumoniae</i> (Inactivated).....1000 million cells <i>Streptococcus agalactiae</i> (Inactivated).....1000 million cells <i>Staphylococcus aureus</i> (Inactivated).....1000 million cells <i>Haemophilus influenzae</i> (Inactivated).....1500 million cells (Innovator's Specifications)	M/s Laboratorio Farmaceutico S.I.T. Via Cavour 70 27035 Mede (PV), Italy.	1's Blister (7 Film-coated Tablets)/ Rs. 1000/- 60 months (<250C)
Decision of 282nd meeting of Registration Board: Keeping in view valid legalized CoPP indicating product availability in country of origin and approval of Austria (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.			

Furthermore, Registration Board in its 297th meeting held on 12-15th January, 2021 approved change in address of importer M/s RG Pharmaceutica (Pvt.) Ltd., Suit # 703, Progressive Square, P.E.C.H.S., Block-6, Sharah e Faisal, Karachi to M/s RG Pharmaceutica (Pvt.) Ltd., BF1-01 First Floor, Gate No. 1, Bahria Orchard, Main Raiwind Road, Lahore and godown at 247-Sundar Industrial State, Lahore. The firm informed through TID: 27J-HAG-89G5 dated 17.07.2025 that they have submitted following documents on 20.05.2025 w.r.t their above product:

- Application for change of excipient with fee.
- Submission of fresh stability data of Zone-IV-A for 5 Years of shelf life.
- Updated original notarized CoPP of country of origin.
- Application of change in address of importer to M/s RG Pharmaceutica (Pvt.) Ltd Plot No. 247-Sundar Industrial State, Lahore

The description and other details as per submitted CoPP is as under:

Sr. No.	Brand name and composition	Name of manufacturer/ product license holder	Packing and shelf life
1.	BUCCALIN (Gastroresistant Tablets for Adults & Children) Each tablet contains: <i>Streptococcus pneumonia I, II ,III</i> 1 billion bacteria inactivated <i>Streptococcus agalactiae</i> 1 billion bacteria inactivated <i>Staphylococcus aureus</i> 1 billion bacteria inactivated	M/s Laboratorio Farmaceutico SIT S.r.l Via Cavour 70-27035 Mede (PV), Italy.	PVC/Aluminum Blister of 4's & 7's Shelf Life: Five Years Store below 25°C

	Haemophilus influenzae.....1 billion bacteria inactivated (Innovator's Specifications)		
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379. As per CoPP issued by AIFA Italy, the above product is registered and available for sale in Italy, however above product was also approved by the Board keeping in view approval in Austria hence undersigned also verified the registration status of the product from database of Austrian Drug Regulatory Authority (Federal Office for Safety in Health Care, Medical Market Surveillance). As per said database the product is registered in Austria, however not available for sale in market. https://aspreghister.basg.gv.at/aspreghister/faces/aspreghister.jspx;jsessionid=XflT4eW7Wyte8fNu9EYpMC17cj4lH8UZJ1XaiVBa9jD02H3JBDtj!999246121?_adf.ctrl-state=15arxddkc_4 . The product is also registered in Swissmedic but the availability in market cannot be confirmed from the database <https://www.swissmedicinfo.ch/ViewMonographie> .

Decision of Registration Board in 352nd meeting:

Registration Board deferred the case for confirmation of availability/ free sale status of product in Austrian Market. Moreover, a reference shall be sent to Center of Disease Control, National Institute of Health for their views regarding the need of the above-mentioned oral vaccine.

Accordingly, as per above decision a reference was forwarded to Center of Disease Control, National Institute of Health, Islamabad vide DRAP letter 9-27/2022-AD(BD)(PRV)-001 dated 20th February 2026. In response Dr Mumtaz Ali Khan, Chief CDC, NIH has forwarded his opinion vide F.No.1-31/Misc/CDC/2026 dated 08th April 2026:

“The product profile has been examined and reviewed relevant scientific literature, European regulatory decisions and most pertinently Pakistan's own national disease surveillance data generated through the Integrated Disease Surveillance and Response (IDSR) system, as published in the Weekly Public Health Bulletins (PHB) of the Center for Disease Control (CDC), NIH Islamabad. The following opinion is submitted for the Board's consideration:

a. Product Profile

BUCCALIN is a bacterial lysate immunostimulant in gastro resistant tablet form, manufactured by M/s Laboratorio Farmaceutico SIT S.r.l., Italy. Each tablet contains heat inactivated bacterial bodies of four pathogenic species; Streptococcus pneumoniae (Types I, II, III), Streptococcus agalactiae, Staphylococcus aureus, and Haemophilus influenzae at 1 billion organisms each. It is intended for both adults and children and proposed for use in the prophylaxis of Recurrent Respiratory Tract Infections (RRTI).

b. Mechanism of Action

Bacterial lysate products operate as non-specific oral immunostimulants. On oral administration, the inactivated bacterial antigens interact with gut-associated lymphoid tissue (GALT), stimulating innate and adaptive immune pathways. Published literature demonstrates activation of dendritic cells and innate lymphoid cells (ILC3), enhancement of Th1 immune responses, and an increase in secretory and serum immunoglobulin A (IgA) and IgG levels. A "trained immunity" effect has also been described, conferring broader protection against heterologous respiratory pathogens beyond those represented in the lysate.

c. Review of Clinical Evidence

The principal published evidence for BUCCALIN includes a multicenter, randomized, double-blind, placebo-controlled trial (Carlone et al., 2014; EudraCT: 2011-005187-25) in patients with RRTI, which demonstrated a statistically significant reduction in the number of days with infectious episodes in the treated group compared to placebo, with a favorable safety profile. An earlier randomized trial in patients with chronic purulent sinusitis reported significant improvement in symptom scores and radiological findings in the bacterial lysate arm. Broader systematic reviews of bacterial lysates as a class (De Grazia et al., 2024; Biomolecules) confirm that most studies

show a reduction in frequency and severity of RTIs in pre-treated patients without significant safety concerns.

However, it has been observed that significant limitations persist in the evidence base. The European Medicines Agency (EMA), following a formal Article 31 referral review concluded in September 2019 (EMA/CHMP/349538/2018), determined that the clinical data for bacterial lysate products including BUCCALIN are of limited overall quality due to small sample sizes, heterogeneous study populations, and methodological variability. The EMA's CHMP accordingly:

- i. Restricted the approved indication to prophylaxis of recurrent respiratory tract infections only, explicitly excluding treatment of active RTIs and pneumonia prophylaxis;
- ii. Required submission of further post-marketing efficacy data;
- iii. Raised specific concerns about pediatric use, recommending restriction to children above two years of age and requiring an acceptability study.

The applicant may also be asked to provide clinical trial data generated in low and middle income country (LMIC) settings, specifically in South-Asian populations, given that immunological responsiveness, gut microbiome composition, baseline infectious burden and nutritional immunity profiles in Pakistani patients may differ substantially from the European reference populations on which the existing evidence base is founded. Extrapolation of European efficacy data to Pakistani populations carries significant uncertainty and should be explicitly acknowledged in all product labelling.

d. Regulatory Status

BUCCALIN is registered via national procedures in several European Union Member States, including Italy (the country of manufacture). Its current registration is conditional upon the updated indications per the EMA 2019 directive. It does not hold WHO prequalification and is not listed on the WHO Essential Medicines List.

e. Epidemiological Burden in Pakistan - Evidence from IDSR/PHB Surveillance Data

The Integrated Disease Surveillance and Response (IDSR) system of NIH Pakistan, covering 169 districts across the country, generates weekly syndromic surveillance data on priority diseases including Influenza-Like Illness (ILI), Acute Lower Respiratory Infection in children under five years (ALRI <5 years) and Severe Acute Respiratory Infection (SARI). Analysis of recent IDSR Weekly Public Health Bulletins (October 2025 – January 2026) reveals a consistently high and sustained burden of respiratory illness across Pakistan:

• **Surveillance Data Summary: ILI and ALRI <5 Years (October–December 2025)**

The following suspected case counts are extracted directly from IDSR-PHB national surveillance tables, which represent syndromic reporting from all implementing provinces and regions. Punjab data was not reportable (NR) during this period and is excluded from national totals.

Several important observations emerge from these data:

- i. ILI consistently ranks among the top three most frequently reported diseases nationally, following Malaria and Acute Diarrhea, across all reporting weeks in this period. By Week 50 (December 2025), ILI had climbed to second position in overall disease burden nationally, reflecting the onset of winter respiratory season.
- ii. ALRI in children under five years consistently ranks as the fourth most reported disease nationally, with over 20,000 suspected cases per week, representing an extremely high burden in the most vulnerable age group.
- iii. A clear increasing trend in ILI and SARI cases was documented between Weeks 44 and 50, with ILI rising from 53,377 to 61,429 per week, an increase of approximately 15%, consistent with seasonal amplification of respiratory illness during the October-to-February cold season.

- iv. Geographically, the burden is diffuse. In Week 44, ILI was reported from all regions: Sindh (33,903), KP (6,998), Balochistan (7,627), AJK (2,495), GB (333), and ICT (2,021). ALRI <5 years was similarly widespread: Sindh (14,429), AJK (1,340), KP (1,811), Balochistan (2,078), and GB (879)
- v. Islamabad Capital Territory's own surveillance consistently identified ILI as the single most frequently reported disease, ahead of all other notifiable conditions, with ALRI <5 years as the third most reported, directly relevant to the policy-making context of this review.

These figures represent syndromic (suspected) cases only and are acknowledged to be an undercount of true disease burden due to incomplete healthcare access, care-seeking behavior, and IDSR compliance limitations (national compliance was 73–75% during this period).

f. Laboratory-Confirmed Viral Etiology

Complementing the syndromic burden above, a prospective multicenter sentinel surveillance study conducted across seven tertiary hospitals in Pakistan from November 2022 to June 2025 (published January 2026) provides the most current laboratory data on the viral etiology of SARI in Pakistan. Among 11,451 specimens tested by RT-PCR, 24.6% tested positive for one of three respiratory viruses — RSV accounting for 14.4% positivity (n=1,648), influenza 7.5% (n=855, predominantly H1N1pdm09 and H3N2), and SARS-CoV-2 at 2.8% (n=315). Bacterial co-infections, particularly with organisms included in the BUCCALIN formulation (*S. pneumoniae*, *S. aureus*, *H. influenzae*), are well-documented as secondary pathogens in such viral SARI episodes.

3. In view of the aforementioned, particularly the quantified and sustained national burden of ILI and ALRI <5 years documented through Pakistan's own IDSR surveillance system; Center for Disease Control, NIH Islamabad is of the considered opinion that:

- i. There is a clear and data-supported public health rationale for prophylactic interventions targeting recurrent respiratory illness in Pakistan. The IDSR/PHB data unambiguously demonstrate that ILI and ALRI in children under five are among the highest-burden conditions reported nationally, with tens of thousands of suspected cases reported each week. This burden intensifies during the October–February winter respiratory season, precisely the period when BUCCALIN-class prophylaxis would be most relevant.
- ii. The evidence base for BUCCALIN is partially supportive but not definitive. The available RCT data suggest a modest prophylactic benefit in RRTI, but the overall quality of evidence remains low to moderate, and large-scale confirmatory trials are lacking.
- iii. The product may be considered for conditional registration, subject to the following safeguards:
 - a) The indication shall be restricted strictly to prophylaxis of recurrent respiratory tract infections, consistent with the EMA 2019 directive. Use for treatment of acute active infections or pneumonia prophylaxis shall not be permitted.
 - b) Pediatric use must be limited to children two years of age and above, with explicit labelling and package insert guidance for caregivers.
 - c) The applicant (M/s RG Pharmaceutica) must furnish a local post-marketing surveillance plan and commit to submission of periodic safety update reports.
 - d) The product must not be promoted as a vaccine or as a substitute for any licensed immunization included in Pakistan's Expanded Programme on Immunization (EPI), including pneumococcal conjugate vaccine (PCV) and influenza vaccine.
 - e) Prescriber education materials must clearly communicate the immunostimulant, not vaccine, nature of the product, the exclusive prophylactic indication, and the limited quality of the supporting evidence base.

4. This opinion is provided as a technical and epidemiological advisory input from the Center for Disease Control; NIH and the relevant supporting references / literature have also been attached for your

review and record. It should be read in conjunction with DRAP's comprehensive pharmaceutical, clinical and regulatory evaluation of the dossier.

Decision:

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

- i. **Evidence of registration/ availability of applied product in other European Countries including Austria.**
- ii. **Periodic Benefit Risk Evaluation Reports (PBRERs) of this product generated since its international birth date as per format defined in ICH E2C (R2).**

Case No. 2 Request for issuance of Renewal of Registration by M/s Hoechst Pakistan Limited Karachi

M/s Hoechst Pakistan Limited, Plot No. 23 Sector 22 Korangi Industrial Area has submitted request vide SQ9-7BM-7A33 and 11P-ETZ-L3YV for issuance of renewal of registration on their following registered vaccines. The last renewal application of below products was submitted after due date but within sixty days. Details are as under:

Sr. No.	Reg. No.	Product	Date of Registration	Renewal submission details	Decision/ validity
1.	077526	Imovax Polio Vaccine (Poliomyelitis Vaccine, Suspension for Injection in Multidose Vial) One dose of 0.5ml contains: Poliomyelitis virus (inactivated) Type 1 (Mahoney strain): 29 DU*; Type 2 (MEF 1 strain): 7 DU*; Type 3 (Saukett strain): 26 DU* *DU: D-antigen Unit *These antigenic quantities are strictly the same those as previously expressed as 40-8-32 antigen units, for type 1, 2 & 3 viruses respectively when measured by another suitable immunochemical method. #cultured on vero cell European Pharmacopeia. MAH: Sanofi Winthrop Industrie 82 Avenue Raspail 94250 Gentilly, France Manufacturer & Batch Release: Sanofi Winthrop Industrie Parc Industriel D' Incarville, Voie De L Institut, P. O. Box 101, Val De Reuil, 27100, France	15.05.2014 Approval of Change of Title: 18.12.2024	25.06.2026 vide TID: RY6-5N1-4Y6U Rs. 60000/-	Renewal is granted w.e.f. 15.05.2024 to 14.05.2029
2.	025266	Vaxigrip (Purified Inactivated Influenza Vaccine)	07.08.2000 Transfer of Registration:	29.12.2023 Rs. 300000/-	Renewal is granted w.e.f. 04.03.2023

	Each dose (0.5ml) contains: Influenza virus (inactivated, fragmented) of the following strains*: A/Victoria/4897/2022 (H1N1) pdm09-similar strain (A/Victoria/4897/2022, IVR-238).....15 micrograms HA** A/Croatia/10136RV/2023(H3N2)-analogous strain (A/Croatia/10136RV/2023, X-425A).....15 micrograms HA** B/Austria/1359417/2021-like strain (B/Michigan/01/2021, wild type).....15 micrograms HA** *grown on embryonated eggs from hens from healthy farms **hemagglutinin MAH: Sanofi Winthrop Industrie 82 Avenue Raspail 94250 Gentilly, France Manufacturer: Sanofi Winthrop Industrie Parc Industriel D' Incarville, Voie De L Institut, P. O. Box 101, Val De Reuil, 27100, France	04.03.2008 Approval of Change of Title: 18.12.2024		to 03.03.2028
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Decision: Registration Board granted the renewal of above registered products as per validity mentioned against each.

Case No. 03: 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 347 th 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 ^o C -8 ^o C)	Keeping in view the legalized GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.

	CENTRE-NIEA H9 Each dose (0.5 ml) of vaccine contains: Newcastle Disease Virus, Strain La Sota $\geq 10^{8.5}$ EID50 Infectious Bronchitis Virus, Strain M41 $\geq 10^{6.5}$ EID50 Egg Drop Syndrome Virus, Strain HSH23 ≥ 1000 HA units Avian Influenza (subtype H9) Virus, Strain WD $\geq 10^{7.5}$ EID50	250ml/500 doses 18 months (2°C -8°C)	Keeping in view the legalized GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.
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Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 5th to 6th November, 2025:

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

Following are the observations & conclusion of Panel:

1. Observations

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

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

2. Conclusion

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

i) **CENTRE-NDFLU H9**

Each dose (0.5 ml) contains:

Minimum concentration of Avian Newcastle Disease Virus, LaSota strain ... $10^{8.175}$ EID50

Minimum concentration of Avian Influenza (subtype H9) Virus, WD strain ... $10^{7.175}$ EID50

ii) **CENTRE-NIEA H9**

Each dose (0.5 ml) of vaccine contains:

Newcastle Disease Virus, Strain La Sota $\geq 10^{8.5}$ EID₅₀
Infectious Bronchitis Virus, Strain M41 $\geq 10^{6.5}$ EID₅₀
Egg Drop Syndrome Virus, Strain HSH23 ≥ 1000 HA units
Avian Influenza (subtype H9) Virus, Strain WD $\geq 10^{7.5}$ EID₅₀

Decision 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:

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.

Case No. 04: 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 $\geq 10^6$ EID₅₀

Avian Infectious Bronchitis, strain H-120 $\geq 10^{3.5}$ EID₅₀

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

Each dose (1ml) contains:

Fowl pox virus, strain Cutter $\geq 10^{2.8}$ TCID₅₀

Solvent contains:

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

Brilliant blue dye E 133 - 0.5 g

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

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

Each one dose contains:

Virus of Newcastle disease, strain “La-Sota” DK-124 $\geq 10^{6.0}$ EID₅₀ per dose, obtained on SPF chicken embryos.

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

One dose of the vaccine contains;

Newcastle disease virus, strain “La-Sota” DK-124 $\geq 10^{6.0}$ EID₅₀

Avian infectious bronchitis virus, strain H-120 $\geq 10^{3.5}$ EID₅₀.

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

Each dose (0.1 ml) contains:

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

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

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

2- Mr. Nafees ur Rehman, Deputy Director (H&OTC), DRAP, Islamabad.

Following are the observations & conclusion of Panel:

Observation

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

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

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

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

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

One dose (0.5 ml) contains;

Inactivated antigens in the titer before inactivation:

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

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

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

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

Each dose contains:

Newcastle disease, strain Hitchner B1 $\geq 10^6$ EID₅₀

Avian Infectious Bronchitis, strain H-120 $\geq 10^{3.5}$ EID₅₀

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

Each dose (1ml) contains:

Fowl pox virus, strain Cutter $\geq 10^{2.8}$ TCID₅₀

Solvent contains:

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

Brilliant blue dye E 133 - 0.5 g

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

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

Each one dose contains:

Virus of Newcastle disease, strain “La-Sota” DK-124 $\geq 10^{6.0}$ EID₅₀ per dose, obtained on SPF chicken embryos.

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

One dose of the vaccine contains;

Newcastle disease virus, strain “La-Sota” DK-124 $\geq 10^{6.0}$ EID₅₀

Avian infectious bronchitis virus, strain H-120 $\geq 10^{3.5}$ EID₅₀.

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

Each dose (0.1 ml) contains:

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

Decision 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:

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.

Case No. 05: Imported Human Biologicals from Non-Reference countries.

1.	Name, address of Applicant / Importer	M/s SIND MEDICAL STORES, Plot No. 13-B, Block 6, PECHS, Shahrah e Faisal Karachi – 75400, Pakistan
	Details of Drug Sale License of importer	License No: 0257 Address 13-B/ B-10, Block 6, PECHS, Shahrah e Faisal Karachi. Validity: 01-07-2024
	Name and address of marketing authorization holder (abroad)	<u>For Vaccine manufacturing:</u> NAME: Changchun BCHT Biotechnology Co. Address: 138 Zhuoyue Street, Changchun High-tech Zone, Changchun, Jilin, P. R, CHINA. <u>For Sterile Water for Injection (Pre-filled Syringe) PFS Diluent:</u> NAME: Changchun BCHT Biotechnology Co. Address: 1260 Huoju Road, Changchun High-tech Zone, Changchun, Jilin, P. R, CHINA.
	Name, address of manufacturer(s)	<u>For Vaccine manufacturing:</u> NAME: Changchun BCHT Biotechnology Co. Address: 138 Zhuoyue Street, Changchun High-tech Zone, Changchun, Jilin, P. R, CHINA. <u>For Sterile Water for Injection (Pre-filled Syringe) PFS Diluent:</u> NAME: Changchun BCHT Biotechnology Co. Address: 1260 Huoju Road, Changchun High-tech Zone, Changchun, Jilin, P. R, CHINA.
	Name of exporting country	CHINA.
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted legalized COPP No. Jilin 20230045 valid till 24-09-2025 issued by Jilin Medical Product Administration, China. The CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of product specific authorization from Director, Exports of M/s Changchun BCHT Biotechnology Co. According to the letter, the firm M/s: Changchun BCHT Biotechnology Co. authorizes “ M/s SIND MEDICAL STORES for the purpose of registration, import, promotion, marketing, quoting in private & public (Government) tenders.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Form 5 F 12345 Dated: 30-11-2022
Details of fee submitted	Rs: 150,000/- Dated: 13-10-2022 Deposit Slip No.190093201
The proposed proprietary name / brand name	VAXAPOX Live Attenuated Varicella Vaccine, Lyophilized + 0.5ml SWFI in PFS (Diluent in Pre-filled Syringe)
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	0.5 ml per single human dose shall contain not less than 3.3 lg PFU (2000PFU) of live varicella-zoster virus (Oka strain).
Dosage form of applied drug	Injection.
Pharmacotherapeutic Group of (API)	Biological product (Vaccine)
Reference to Finished product specifications	Chinese pharmacopoeia
Proposed Pack size	Box of 1 Dose Vial + 0.5ml SWFI (Sterile Water for Injection) as Diluent in PFS (Vaccine with Diluent in PFS combo pack):
Proposed unit price	As per SRO
Shelf Life	36 months
Storage Conditions	2-8 °C
The status in reference regulatory authorities	Varilrix - GSK
For generic drugs (me-too status)	Okavax – Sanofi Aventis, Varivac – Hi-Warble
Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.,
Name, address of drug substance manufacturer	<u>For Vaccine manufacturing:</u> NAME: Changchun BCHT Biotechnology Co. Address: 138 Zhuoyue Street, Changchun High-tech Zone, Changchun, Jilin, P. R, CHINA. <u>For Sterile Water for Injection (Pre-filled Syringe) PFS Diluent:</u> NAME: Changchun BCHT Biotechnology Co. Address: 1260 Huoju Road, Changchun High-tech Zone, Changchun, Jilin, P. R, CHINA.

Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data This stability study is carried out based on Quality Standard of Varicella Vaccine, Live (Cell Factory) (MQS07088) and Standard Operation Manual for Inspection of Bulk of Varicella Vaccine, Live (SOM07098). The quality of the Varicella Vaccine, Live is relatively stable during the six-month study period, and the study results conform to the standard.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
Container closure system of the drug product	• B04A (13.3 × 6.1 mm, Aluminum-plastic caps) • B04B (13.3 × 6.1 mm, Aluminum-plastic caps for water distribution) • B04C (13.3 × 6.1 mm, Aluminum-plastic caps) • B04D (13.3 × 6.1 mm, Aluminum-plastic caps with a new logo) • B04D (13.3 × 6.1 mm, Aluminum-plastic caps with a new logo)
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data This stability study is carried out in accordance with Quality Standard of Varicella Vaccine, Live (Cell factory), Standard Operation Procedure for Final Product Inspection of Varicella Vaccine, Live (Cell factory) and Quality Standard of Varicella Vaccine, Live Final Product. The quality of this batch Varicella Vaccine, Live is basically stable during study period, all test results conform to the stipulations of standard.
Module-IV Non-Clinical	Non clinical study in order to confirm the safety profile of the product, Test on mice Prepare the mice of 18~22g and weigh their weight before injection. Use 5 mice for each batch of the sample and each mouse shall be intraperitoneally injected for 0.5ml. Test on guinea pig Prepare the guinea pig well of 250~350g and weigh their weight before injection. Use 2 guinea pigs for each batch of the sample and each guinea pig shall be intraperitoneally injected for 5ml. Observe for 7 days. Result The mice and guinea pigs were all alive and healthy without abnormal reaction during the observation period and the weights were increased at the end of the period.
Module-V Clinical	Clinical trial: The results of this clinical study showed that the trial vaccine was used in 660 healthy children aged 1-12, and no serious local and systemic adverse reactions were observed. The positive conversion and 4-fold growth rate of antibody in the trial vaccine group were 98.31% by FAMA, and there was no significant difference compared with the control vaccine group (99.42%).

Decision:

Keeping in view CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

Case No. 6: Veterinary Vaccines (Hard Cases) considered in 9th 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 Expert Working Group in its 9 th meeting	Decision of RB
1.	Importer: M/s U.M. Enterprises, Plot # 12, Sector 15 Korangi Industrial Area, Karachi, Pakistan. Manufacturer: M/s CENTRO DIAGNOSTIC VETERINARIO Address: Calle 4N° 86 esquina 9 Pilar Industrial Pilar CP (B 1629MXA) Buenos Aires, Argentina.	CDVac REPROMAX (Injectable solution) Active ingredients per dose: Compound Quantity per dose Inactivated culture of Bovine Viral Diarrhoea Virus $\geq 6.0 \times 10^6$ CID50% Inactivated culture of Infectious Bovine Rhinotracheitis virus (IBR) $\geq 2.0 \times 10^7$ TCID50% ≥ 20 mg Inactivated culture of Campylobacter fetus fetus ≥ 20 mg Inactivated culture of Campylobacter fetus venerealis $\geq 1.0 \times 10^8$ bacteria Inactivated culture of Histophilus somni $\geq 5.0 \times 10^9$ bacteria Inactivated culture of Leptospira interrogans serovar Canicola $\geq 2.5 \times 10^8$ bacteria Inactivated culture of Leptospira interrogans serovar Hardjo $\geq 2.5 \times 10^8$ bacteria Inactivated culture of Leptospira interrogans serovar Icterohaemorrhagiae $\geq 5.0 \times 10^9$ bacteria Inactivated culture of Leptospira interrogans serovar Pomona Inactivated culture of Leptospira interrogans serovar Wolffi $\geq 5.0 \times 10^9$ bacteria $\geq 2.5 \times 10^8$ bacteria Inactivated culture of Leptospira borgpetersenii serovar	250ml 24 months (2-8°C)	EWG in its 9 th meeting considered the data provided by the firm and decided to ask the firm to provide detailed studies of strains regarding their similarity to existing strains of Pakistan and their need.	Keeping in view the recommendations of EWG; Registration Board deferred the case for submission of detailed studies of strains regarding their similarity to existing strains of Pakistan and their need.

		Tarassovi $\geq 2.5 \times 10^8$ bacteria			
2.	Importer: M/s UMEX Biopharma Pvt. Limited, Plot No.44 A & 45 A NACCLASS No.24, DEH DIL TALUKS. Korangi Industrial Area. Karachi, Pakistan Manufacturer: PT. VAKSINDO SATWA NUSANTARA Jl. Mercedes Benz No. 12, Cicadas, Gunung Putri, Bogor, West Java 16964, Indonesia.	VAKSIMUNE CORYZA L VACCINE Each dose (0.5 ml) contains: Avibacterium paragallinarum Serotype A of 0083 strain, at least.... 108.0 CFU Avibacterium paragallinarum Serotype B of SPROSS strain, at least.....108.0 CFU Avibacterium paragallinarum Serotype B V1 strain, at least..... 108 CFU Avibacterium paragallinarum Serotype C of Modesto strain, at least.....108 CFU		EWG in its 9th meeting considered the data provided by the firm and decided to recommend the product for grant of registration.	Keeping in view recommendation of EWG; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.
3.	Importer: UMEX Biopharma Pvt. Limited, Plot No.44 A & 45 A NACCLASS No.24, DEH DIL TALUKS. Korangi Industrial Area. Karachi, Pakistan Manufacturer: PT VAKSINDO SATWA NUSANTARA (Plant I) Jl.Mercedes Benz No.12 Cicadas, Gunung putri, Bogor, West java 16964, Indonesia MAH: PT VAKSINDO SATWA NUSANTARA (Plant II) Jl. Barokha No.7 RT 001/RW 008 Wanaherang, Gunung putri, Bogor, West java 16965, Indonesia	VAKSIMUNE NDL-IBPLUS-EDS VACCINE Each 0.5ml contains: At least: - 108.5 EID50/ dose of Newcastle Disease Genotype VII N018 strain - 105.9 EID50/ dose of Infectious Bronchitis Massachusetts-41 strain - 105.9 EID50/ dose of Infectious Bronchitis serotype Qx, B003 strain - 105.9 EID50/ dose of Infectious Bronchitis serotype 771, B004 strain - 107.5 EID50/ dose of Egg Drop Syndrome'76 E001 strain		EWG in its 9th meeting considered the data provided by the firm and decided to recommend the product for grant of registration.	Keeping in view recommendation of EWG; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.
4.	Importer: UMEX Biopharma Pvt. Limited, Plot No.44 A & 45 A NACCLASS No.24, DEH DIL TALUKS. Korangi	VAKSIMUNE NDL-IBPLUS VACCINE Each 0.5ml contains: At least:		EWG in its 9th meeting considered the data provided by the firm and decided to recommend the	Keeping in view recommendation of EWG; Registration Board approved the product subject to compliance of

	Industrial Area. Karachi, Pakistan. Manufacturer: PT VAKSINDO SATWA NUSANTARA (Plant I) Jl.Mercedes Benz No.12 Cicadas, Gunung putri, Bogor, West java 16964, Indonesia MAH: PT VAKSINDO SATWA NUSANTARA (Plant II) Jl. Barokha No.7 RT 001/RW 008 Wanaherang, Gunung putri, Bogor, West java 16965, Indonesia	- 108.5 EID50/ dose of Newcastle Disease Genotype VII N018 strain - 105.9 EID50/ dose of Infectious Bronchitis Massachusetts-41 strain - 105.9 EID50/ dose of Infectious Bronchitis serotype Qx, B003 strain - 105.9 EID50/ dose of Infectious Bronchitis serotype 771, B004 strain		product for grant of registration.	current Import Policy for finished drugs.
5.	Importer: UMEX Biopharma Pvt. Limited, Plot No.44 A & 45 A NACLASS No.24, DEH DIL TALUKS. Korangi Industrial Area. Karachi, Pakistan. Manufacturer: PT VAKSINDO SATWA NUSANTARA (Plant I) Jl.Mercedes Benz No.12 Cicadas, Gunung putri, Bogor, West java 16964, Indonesia MAH: PT VAKSINDO SATWA NUSANTARA (Plant II) Jl. Barokha No.7 RT 001/RW 008 Wanaherang, Gunung putri, Bogor, West java 16965, Indonesia	VAKSIMUNE CORYZA LE PLUS VACCINE Each 0.5ml contains: At least: - 108.0 CFU/ dose of Avibacterium paragallinarum serotype A, 0083 strain - 108.5 CFU/ dose of Avibacterium paragallinarum serotype B, V5 strain - 108.0 CFU/ dose of Avibacterium paragallinarum serotype C, Modesto strain - 108.5 CFU/ dose of Avibacterium paragallinarum serotype C, V26 strain		EWG in its 9th meeting considered the data provided by the firm and decided to recommend the product for grant of registration.	Keeping in view recommendation of EWG; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.
6.	Importer: UMEX Biopharma Pvt. Limited, Plot No.44 A & 45 A NACLASS No.24, DEH DIL TALUKS. Korangi Industrial Area. Karachi, Pakistan. Manufacturer:	VAKSIMUNE ILT VACCINE Each 0.5ml vial contains: At least 102.5EID50/ dose of Infectious Laryngotracheitis virus of Hudson strain		EWG in its 9th meeting considered the data provided by the firm and decided to ask the firm to provide detailed studies of Hudson strain regarding its	Keeping in view the recommendations of EWG; Registration Board deferred the case for submission of detailed studies of Hudson strain

	PT VAKSINDO SATWA NUSANTARA (Plant II) Jl. Barokha No.7 RT 001/RW 008 Wanaherang, Gunung putri, Bogor, West java 16965, Indonesia MAH: PT VAKSINDO SATWA NUSANTARA (Plant II) Jl. Barokha No.7 RT 001/RW 008 Wanaherang, Gunung putri, Bogor, West java 16965, Indonesia			similarity to existing strains of Pakistan and its need.	regarding its similarity to existing strains of Pakistan.
7.	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		EWG in its 9th meeting considered the data provided by the firm and decided to ask the firm to provide detailed studies of Genotype V of ND virus regarding its similarity to existing strains of Pakistan and its need.	Keeping in view the recommendations of EWG; Registration Board deferred the case for submission of detailed studies of Genotype V of ND virus regarding its similarity to existing Genotype of Pakistan.
8.	Importer: Forward Solutions, Plot No. 19-B, Qazalbash Chowk, Abdul Sattar Edhi Road, District Lahore Manufacturer: M/s Fatro S.p.A, Via Molino Emili, 2 – 25030 Macclodio (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 in its 9th meeting considered the data provided by the firm and decided to ask the firm to provide detailed studies of NEV 39 regarding its similarity to existing strains of Pakistan and its need.	Keeping in view the recommendations of EWG; Registration Board deferred the case for submission of detailed studies of NEV 39 strain regarding its similarity to existing strains of Pakistan.

Case No. 7: Correction of Registration Application of already registered Veterinary Vaccine.

Following product of M/s Umex Biopharma Pvt. Ltd., Karachi was approved in 345th meeting of Registration Board and registration letter was issued as per following details:

Reg. No.	Name of Manufacturer	Brand Name & Composition	Pack Size, Shelf Life & Storage Conditions
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131631	M/s PT Vakindo Satwa Nusantara, Jl. Barokha No.7 RT 001/RW 008 Wanaherang, Gunung putri, Bogor, west Java. 16965, Indonesia.	Vaksimure POX (Liquid Form, Live Vaccine) Each 0.5ml contains: Fowl Pox virus of Beaudette strain.....at least $10^{3.5}$ EID ₅₀ As per Innovator's Specifications	500ml (1000 Doses) /De-controlled 24 Months (2°C-8°C)
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The firm now submitted an application for correction in registration application stating that the dossier was incorrect that was submitted at the time of registration. Following is the correction

Approved Composition & Pack Size	Proposed Composition
Each 0.5ml contains: Fowl Pox virus of Beaudette strain.....at least $10^{3.5}$ EID ₅₀ 500ml (1000 Doses)	Each 0.01ml contains: Fowl Pox virus of Beaudette strain.....at least $10^{3.0}$ EID ₅₀ 10ml Vial (1000 Doses)

The firm has submitted the FSC No. 20188/PI.500/F/04/2026 dated 20-04-2026 in support of their claim. It is pertinent to mention that the firm submitted another FSC No. 12036/PI.500/ F /07/2022 dated 12-07-2022 with initial application and registration letter was issued as per initial Form-5A & FSC . Now, firm submitted another FSC with this application and requested to correct the strength as indicated in above table. However, it is to inform the Board that registration number in both the FSCs are different which is indicating that this product is different from the previous one. The firm has also submitted fee of Rs. 313,500/- with this application.

Decision:

Registration Board acceded to the request of the firm and decided to cancel existing Registration of Vaksimune POX (Reg. No. 131631) and to grant new registration as applied by the firm subject to compliance of current Import Policy for finished drugs and submission of valid legalized/ apostille revised FSC indicating actual availability of product instead of only indicating admitted to be sold.



Drug Regulatory Authority of Pakistan
(Pharmaceutical Evaluation & Registration Division)



Item No. V

Supplementary Minutes

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Title	Description
1	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	VENUS PHARMA 23-KM MULTAN ROAD, LAHORE (000300)
	Application Form Dy. No / Tracking ID & date of submission	(T3B-ZU8-3Y7X, 2025-05-09)
	Detail of Fee Submitted	37000.0, 2025-04-07,
	The proposed proprietary name / brand name	Dexmedine 100mcg/ml injection
	Label Claim	Each ml contains: Dexmedetomidine 100mcg (as Dexmedetomidine HCl...USP) (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x2ml , As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30 degree celsius temperature
	For generic drugs (me-too Status)	Precedix Injection 100mcg/ml by M/S Brook Pharma Private Limited.
	Pharmacotherapeutic Group of (API)	It is a selective alpha-2 adrenergic receptor agonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S Shandong Chenghui Shuangda Pharmaceutical Co. ,Ltd
	Detail of stability batches of drug product	02 batches having batch no.(TR-021,TR-022) ,Batch sizes :2000 ampoules/batch are developed and performed stabilities for 06months and continued upto 24months.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Final clearance certificate no.RO-A673F8
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is performed against brand leader namely, Precedix Injection 100mcg/ml by M/S Brook Pharma Private Limited.While, Comparative dissolution profile is not applicable in injectables.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches having batch no. 5216121501,5216121502,5216121503 are taken and stabilities data performed on both accelerated conditions(Temp:40± 2°C RH:75 ± 5%) for 06 months and Real time stabilities conditions at (Temp:30±2°C RH:65 ± 5%) for 6 months
	The status in reference regulatory authorities	Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion by M/S Martindale Pharma, an Ethypharm Group

		Company Address: Jupiter House, Mercury Park, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, UK 9USFDA Approved)
	GMP status of the firm	Ref. No. 04/2024-DRAP(AD-46168323) , Dated:02-01-2024
	Evidence of approval of manufacturing facility	Valid DML No. is 000300
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of Registration Board.	
	The case was deferred in 354th meeting for:	
	The firm shall perform testing as per USP and submit results.	
	Reply: The firm has submitted testing results as per USP monograph for enantiomeric impurity along with chromatograms.	
	Decision	
	Approved	
2	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Snam Pharma 61-G, Phase 1, Commercial Area, DHA, Lahore (05-352-0058-036985D)
	Application Form Dy. No / Tracking ID & date of submission	(W5W-TZ6-867B, 2024-08-29)
	Detail of Fee Submitted	75000.0, 225000 2024-08-28, 2025-08-19
	The proposed proprietary name / brand name	Iflurin
	Label Claim	Iflurin 100ml/bottle Composition: Isoflurane 100ml Chinese Veterinary Pharmacopoeia
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	100ml/bottle-De-Controlled
	Shelf Life (Unit)	2 Year(s)Keep away of the light and store in sealed container and a cool place
	For generic drugs (me-too Status)	New Registration in Pakistan
	Pharmacotherapeutic Group of (API)	Inhalation anesthetic
	Name, address of Manufacturing site:	Ringpu (Tianjin) Bio-Pharmacy Co., Ltd.-No. 6 Liujing Road, Dongli District, Tianjin, Postal Code: 300300-China
	Name, address of Marketing Authorization Holder:	Tianjin Ringpu Bio-Technology Co. Ltd., No. 1 Dongjiu Road, Tianjin Free Trade Area (Airport Economic Area), Tianjin, China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted 6 months accelerated and 24 months real time stability studies data as per zone IV-A conditions.
	Evaluation Remarks	
	Scanned copies of GMP valid till 21-11-2026, FSC and LOA valid till 17-08-2029 are submitted. Firm shall submit fee for pre-approval variation in FPP specifications and since scanned copies of FSC, GMP certificate and LOA submitted, firm shall submit original legalized documents before issuance of registration letter.Sub-committee on veterinary drugs recommended the formulation.	
	Decision	
	Approved	

	Approved as per current import policy and firm shall submit original legalized CoPP/GMP+FSC along with product specific letter of authorization before issuance of letter.	
3	Case Category	Import (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	u.m.enterprises plot no.12 sector 15 korangi industrial area-74900 (313)
	Application Form Dy. No / Tracking ID & date of submission	(12H-2GQ-EMPA, 2024-03-25)
	Detail of Fee Submitted	150000.0, 300000.0 2024-01-23, 2024-01-05
	The proposed proprietary name / brand name	DINOLYS
	Label Claim	Each ml contains; Prostaglandin F2 α Tromethamine...5mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	5 Vials per Box -De-Controlled
	Shelf Life (Unit)	24 Month(s)Store at a cool and dark place
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	Synthetic Prostaglandin Analogue
	Name, address of Manufacturing site:	M/s Ningbo Sansheng Biological Technology Co., Ltd-No.159, Buzheng East Road, Haishu District, Ningbo, Zhejiang, China-China
	Name, address of Marketing Authorization Holder:	M/s Ningbo Sansheng Biological Technology Co., Ltd, No.159, Buzheng East Road, Haishu District, Ningbo, Zhejiang, China, China
	Details of Certificates (CoPP/FSC/cGMP):	Valid Legalized CoPP & GMP has been submitted
	Details of Authorization Letter :	Scanned copies of Legalized FSC, GMP and LOA has been submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	The applicant has provided the required documents.Sub-committee on veterinary drugs recommended the formulation.	
	Decision	
	Approved	
	Approved as per current import policy and firm shall submit original legalized CoPP/GMP+FSC along with product specific letter of authorization before issuance of letter.	

1. REGISTRATION OF DRUGS UNDER DRUGS ACT, 1976.

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

Name of Importer/Manufacturer	Name of Product and Composition
M/s Brand Station 69 Wocland Villas Lahore Near Raiwind Road, Lahore.	Lincospecto BS (Water Soluble Powder)
Product License Holder & Manufacturer: M/s Inner Mangolia Huatian Pharmaceutical Co. Ltd - Economic Development & Experiment Zone Economical Transformation of Resource Dependent City, ChiFeng, Inner Mongolia, P.R. China.	Each gram contains: Amoxicillin trihydrate 200mg Lincomycin hydrochloride 88mg Spectinomycin hydrochloride..... 88mg Vitamin E Acetate 30mg
Decision: Approved as per current import policy and firm shall submit original legalized FSC, GMP and Letter of Authorization before issuance of registration letter	

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

Conclusion

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

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

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

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

We promise again that the penicillin powder-producing workshop area will be isolated from others at all times. This one penicillin-producing workshop (see the attached Layout below) is now only used for Penicillin powder products, which will not be used for other antibiotic powder production. Hope you could give a kind understanding.

Decision 354:

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

Firm Reply:-

Firm has submitted a letter form relevant regulatory Body (Agriculture and animal husbandry China) stating thay “This is to Clarify the production of β -Lactam(Penicillin)veterinary drugs, by Inner Monglia Huatian Pharmaceuticals” Ltd. (Veterinary Drug GMP Certificate No.05019,2022.

The company operates a dedicated production line for β -Lactarn (Penicillin) powder veterinarv drugs' housed in an independent building with a separate air conditioning system. Such as; Amoxicillin soluble powder, Approval no.07040020230103-036, Compound Amoxicillin Powder, Approval No.07040020250115-089 etc.”

Decision:

Registration Board accept the document submitted by the firm and approved to proceed for issuance of registration letter.

2.	Name and address of manufacturer / Applicant	M/s Noble Pharma, B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobivec-C Injection
	Composition	Each ml Solution Contains: Ivermectin...20mg Clorsulon...10mg
	Diary No. Date of R& I & fee	Dy.No 8323 dated 20-04-2020 Rs.20,000/- dated 22-04-2020
	Pharmacological Group	Antiparasitic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml vial: Decontrolled
	Me-too status	Could not be confirmed in the applied strength
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. It was observed to do a lot of

		improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas. A detailed report would be submitted later on after verification of same through onsite inspection.
	Remarks of the Evaluator ^x	Approval of Veterinary Liquid Vial injection (General) section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015. Shortcomings: - Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. - Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
	Decision: : (M-324) Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months. Firm Reply:- Firm has submitted generic / me-too status) Ivobak Reg No.063825 of M/s. Attabak pharmaceuticals, Islamabad and also requested for 50ml pack size. Decision: Approved subject to submission of fee for specification correction as per SRO.	
3.	Name and address of manufacturer / Applicant	Selmore Pharmaceuticals (Pvt.) Ltd., 36 Km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	Amoxizyme Oral Powder
	Composition	Each 1000 gm contain: Amoxicillin trihydrate.....50g Lysozyme chloride.....10g Guaifenesin 35g
	Diary No. Date of R& I & fee	Dy No. 10003: 16.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Penicillin with antiviral and expectorants (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 2.5kg, 5kg; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	MOXIN-L WATER SOLUBLE POWDER. Reg. No. 071053
	GMP status	The firm was inspected on 05.03.2018, 17.08.2018 & 16.10.2018 wherein Renewal of DML was recommended
	Remarks of the Evaluator.	•
	Decision: (M-290) Deferred for clarification from the firm regarding source of Lysozyme chloride (biological or synthetic) Firm Reply:- Firm has submitted generic / me-too status) Fen Mox-L Water Soluble Powder Reg No. 111491 of M/s. Aamster laboratories,, Islamabad. Decision: Approved subject to submission of fee for specification correction as per SRO.	

4.	Name and address of manufacture / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name + Dosage Form and Strength	Electromix Granular Powder
	Composition	Each Kg Contains: Calcium.....220g Phosphorus.....160g Magnesium.....65g Sodium.....50g Sulphur.....45g Iron.....1200mg Zinc.....3500mg Manganese.....2300mg Copper.....750mg Cobalt.....12mg Iodine.....55mg Selenium.....5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12781 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Minerals
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	500gm, 1kg, 2.5kg, 5kg; As per SRO
	Me-too-status	
	GMP Status	The firm was inspected on 05-03-2018,17-08-2018 & 16-10-2018 and conclusion of inspection was: In the light of the inspection conducted by the panel and based on the findings the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Selmore Pharma Lahore for following sections: 1- Veterinary Bolus 2- Veterinary Aerosol 3- Veterinary Oral powder 4- Veterinary Oral Liquid 5- Veterinary Liquid Injection 6- Veterinary Penicillin oral powder 7- Veterinary Penicillin dry powder for injection 8- Veterinary Penicillin liquid injection 9- Veterinary Hormone Liquid injection 10- Human Penicillin capsule 11- Human Penicillin dry powder suspension 12- Human Penicillin dry powder injection.
	Previous Remark of Evaluator ^{XI}	• Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Previous Decision (297-DRB)	Deferred for the following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm • Mention the correct salt form of minerals in the applied label claim along with submission of applicable fee
	Evaluation by PEC	• The firm have mentioned the salt form of minerals in the label claim along with submission of Rs 20000/- on deposit slip#0814948 dated 26.03.2021. The revised label claim is as under: Each Kg Contains:

		Calcium carbonate.....220g Dicalcium phosphate (Phosphorus).....160g Magnesium chloride.....65g Sodium sulphate.....50g Magnesium Sulphate.....45g Ferrous sulphate.....1200mg Zinc sulphate 3500mg Manganese sulphate 2300mg Copper sulphate 750mg Cobalt chloride.....12mg Potassium Iodide.....55mg Sodium Selenite.....5mg The firm provided evidence of me-too. Nutrimix-B Powder/granules by M/s Nawan Laboratories (Reg#006306) which could not be verified
	Decision: (M-290) Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm Firm Reply:- Firm has submitted generic / me-too status) Nutrimix-B Reg No. 006306 of M/s. Nawan Pharmaceutical Karachi. Remarks: Nutrimix-B composition is not confirmed from its registration letter due to too old registration however M/s selmore submit its market label showing similar composition. Decision: Approved subject to submission of fee for specification correction as per SRO.	
5.	Name and address of Applicant	M/s. Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s. Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: 12-07-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang, Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang, Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25225 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.40463491104)
	Brand Name +Dosage Form + Strength	Dimipro Plus 2.36gm Granules for Injection
	Composition	Per Unit contains:- Diminazene Aceturate.....1.05g Vitamin B6.....5mg Vitamin B12.....1mg Antipyrine add to.....2.36g
	Finished Product Specification	CVP specifications
	Pharmacological Group	Antiprotozoal
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	2.36gm bag

	International availability	N/A
	Me-too status	Could not be confirmed
	Detail of certificates attached	➤ Original embassy attested CoPP No. 2021042911 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting countries as well as GMP status of the manufacturer Validity: 28-04-2026 ➤ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator ^x	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. Shortcomings: • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to Generic/RRA confirmation. Sub-committee on veterinary drugs recommended the above formulation for veterinary drugs. Decision: Approved subject to submission of fee for specification correction as per SRO. The firm shall submit original legalized CoPP and product specific letter of authorization before issuance of letter.		

Export Facilitation Desk

Complaint/ Request for Regulatory Review and Cancellation of Registration of aprotinin Injection of M/s Novamed (Pvt) Ltd, manufactured under the General Section

Formal complaint has been lodged on PM portal for the consideration of the competent authority regarding the registration and manufacturing facility of Aprotinin Injection as under:

Aprotinin is widely recognized as a biotechnology-derived medicinal product, obtained through complex biological processes and therefore subject to specialized regulatory evaluation. Under the regulatory framework governing biological and biotechnology products in Pakistan, such medicines fall under the jurisdiction of the Biological Drugs Section of the Drug Regulatory Authority of Pakistan (DRAP) for scientific evaluation, registration, and regulatory supervision.

M/s Novamed Pharmaceutical (Pvt) Ltd. 28 Km Ferozpur Road, Lahore Pakistan, has obtained registration for Aprotinin Injection 10000 KIU under the brand name

"Contrykal Injection", bearing Registration No. 008106-Ex, and the product is reportedly being manufactured in the General Liquid Injection Section. This classification appears inconsistent with the regulatory requirements applicable to biotechnology-derived products.

Biological and biotechnology-based medicinal products require specialized technical assessment, including but not limited to evaluation of the biological source, manufacturing technology, purification processes, viral safety, immunogenicity risks, quality control systems, and clinical safety data. These evaluations are specifically designed to be conducted by the Biological Drugs Section in order to ensure compliance with national regulatory standards and international good regulatory practices.

The registration and manufacturing of a biotechnology-derived product under the General Section may bypass the appropriate scientific review and regulatory safeguards required for biological medicines. Such deviation from the prescribed regulatory pathway raises serious concerns regarding regulatory compliance, product quality assurance, and patient safety:-

In view of the foregoing, it is respectfully requested that the competent authority may kindly:

1. Conduct an immediate regulatory review of the registration granted to Contrykal Injection 10000KIU (Aprotinin Injection) to M/s Novamed Pharmaceuticals (Pvt.) Ltd.,
2. Examine whether the product has been registered and classified in accordance with the applicable DRAP regulations governing biotechnology-derived products.
3. Take appropriate regulatory action, including suspension or cancellation of the registration, if the product is found to have been registered in violation of the applicable regulatory provisions or outside the jurisdiction of the relevant section.

It is pertinent to mention that the **Contrykal Injection, (Registration No. 008106-Ex)** has been registered in the name of M/s Novamed on 22nd July 2019 for export purpose. Moreover, same formulation has been granted to firm for export registration with a different brand name **INCONTRAVIN INJECTION (Reg No. 020161-Ex)** vide Tracking ID 35D-BTL-515D dated 27-02-2026. While evaluating said application firm was inquired about the source of drug substance (whether biological or synthetic) wherein firm replied as under:

NovaMed Pharmaceuticals (Pvt.) Ltd. hereby certifies that the Aprotinin powder used as the active pharmaceutical ingredient in Aprotinin injection 10,000KIU is PHARMACEUTICAL GRADE material complying with European Pharmacopoeia 9.0, Monograph (Aprotinin). The active pharmaceutical ingredient (API), Aprotinin, is procured from one of three approved source manufacturers as Synthetic Aprotinin Powder. The relevant Certificates of Analysis (CoA) for the approved API sources are enclosed for reference.

1) Nanchang Wanhua Biochem Products Co., Ltd

2) Hanways Chempharm Co., Limited

3) Qingdao Essenland Biotech Co., Ltd

Aprotinin is a well-characterized, low molecular weight polypeptide with an established amino acid sequence and pharmacopoeial control and is provided as a synthetic powder. It does not involve any recombinant technology, or biologicals.

Decision: Registration Board deliberated the matter and decided to issue show cause to M/s Novamed (Pvt) Ltd, as to why registration of its formulation (Aprotinin injection) should not be cancelled as requisite manufacturing facility is not available.

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

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