MINUTES OF 335TH MEETING OF REGISTRATION BOARD

HELD ON 25TH APRIL, 2024

DRUG REGULATORY AUTHORITY OF PAKISTAN
PRIME MINISTER'S NATIONAL HEALTH COMPLEX.
PARK ROAD, CHAK SHEHZAD
ISLAMABAD.

335th meeting of Registration Board was held on 25th April, 2024 in the Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister's National Health Complex, Park Road, Islamabad.

The meeting was chaired by Dr. Muhammad Fakhruddin Aamir, Chairman,Registration Board, DRAP. The meeting started with recitation of the Holy Verses.

Following members attended the meeting:

1.	Lt. Gen.(R) Prof. Dr. Karamat A. Karmat, (HI-M, SI-M), Former Surgeon General Pakistan, Rawalpindi (On line)	Co-opted Member
2.	Mr. Muhammad Arif Ch, Director, Division of BE&R	Member
3.	Mr. Ajmal Sohail Asif, Director, Division of QA&LT	Member
4.	Ch. Zeeshan Nazir Bajar, Additional Director	Secretary
5.	Mr. Muhammad Aslam, Additional Draftsman, M/o Law &Justice, Islamabad.	Member
6.	Mr. Ghulam Mujtaba, Deputy Director, Rep. of IPO,Islamabad. (Online)	Member
7.	Mr. Sartaj Khan, Senior Drug Analyst. Rep of Director DTL, Govt. of KP	Member
8.	Mr. Adnan Rizvi, Director, DTL, Karachi Sindh (Online)	Member
9.	Dr. Asad Abrar, Director DTL, Govt. of Punjab	Member
10.	Mirza Mehmood Baig, Director, DTL, Govt. of Baluchistan Quetta	Member
11.	Mr. Iftikhar A. Chaudhary, Hospital Pharmacist, Lahore (Online)	Co-opted Member
12.	Dr. Qurban Ali, Ex-Director General, NVL, Veterinary Expert	Co-opted Member
13.	Ms. Sadaf Ahmad, Assistant Director, Rep. of Director,MD&MC Division	Member

Ms. Amber Basharat, Drug Inspector, ICT, Islamabad also attended the meeting to assist the Board in the cases refered by Secretary QC Board, ICT, Islamabad.

Mr. Nadeem Alamgir (Pharma Bureau), Mr. Jalal-ud-Din Zafar & Mr. Hamid Raza (PPMA) and Mr. Amir Ilyas & Mr. Zia ul Haq (PCDA) attended the meeting as observers.

Item No. I. Confirmation of Minutes of 334th meeting of Registration Board

334th meeting of Registration Board was held on 25th January, 2024. Accordingly, draft minutes of the 334th meeting of Registration Board were prepared and circulated among the members through email on 27th January, 2024 for their perusal / approval / comments (if any) by 30th January, 2024. (9:00 am). Lt. General Karamat A. Karamat (R) through email on 29th January, 2024 responded as "*Went through the Page 79 onwards to the end thoroughly & from my side it is OK. Regards*". Mr. Ch. Iftikhar Ahmad through WhatsApp on 29th January, 2024 in ***"Registration Board"*** responded as *"Ok".* Rest of the members did not comment. Hence minutes of 334th meeting of the Registration Board stand approved. Accordingly, fair minutes of 334th meeting were signed and sent to relevant Division for compliance / implementation of decision of Board.

Decision: Registration Board noted the information and unanimously confirmed minutes of 334th meeting of Registration Board.

Item No. II Division of Pharmaceutical Evaluation & Registration

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Name of Evaluator	Title
1.	Mr. Ammar Ashraf Awan	Evaluator PEC-II
2.	Dr. M. Haseeb Tariq	Evaluator PEC-III
3.	Mst. Farzana Raja	Evaluator PEC-IV
4.	Mst. Iqra Aftab	Evaluator PEC-V
5.	Mr. Adil Saeed	Evaluator PEC-IX
6.	Dr. Farhadullah	Evaluator PEC-XI
7.	Mr. Shahid Nawaz	Evaluator PEC-XIII
8.	Ms. Saima Hussain	Evaluator PEC-XV
9.	Ms. Sana Kanwal	Evaluator PEC-XX
10.	Mr. M. Tahir Waqas	Evaluator PEC-XXI
11.	Ms. Maham Misbah	Evaluator PEC-XXIII
12.	Mr. Hafiz Asif Iqbal	Evaluator PEC-XXIV
13.	Ms. Najia Saleem	Evaluator PEC-XXV
14.	Mr. Muneeb Ahmed Cheema	Deputy Director (PE&R)
15.	Mr. Salateen Waseem Philip	Deputy Director (PEC)
16.	Mr. Sarfraz	Assistant Director (PE&R)

Case no. 01 Registration applications for local manufacturing of (Human) drugs of New DML (Veterinary).

Central Licensing Board in its 294th meeting held on 27th December, 2023 approved the grant of DML No. 000990 (by way of formulation) M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad, with following sections: -

i. Dry Powder/Granules/Pellets Section – Veterinary
ii. Oral Liquid Section (General) – Veterinary
iii. Liquid Injectable Section General –Veterinary

Accordingly following applications are presented below against the priority quota of New DML.

1.	**Name and address of manufacturer / Applicant**	**M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad**
	Brand Name +Dosage Form + Strength	**DT-NIX Water Soluble Powder**
	Composition	Each 100 gm contains. Doxycycline HCl …….. 40 gm Tylosin Tartrate …… 20 gm
	Tracking ID/Date of submission & fee	Tracking ID: 93M-MZ4-983U dated 20-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**Dyto-60 Oral Powder of M/s Leads pharma (Reg. # 102024)**
	GMP status	New DML issued on 26-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
2.	**Name and address of manufacturer / Applicant**	**M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad**
	Brand Name +Dosage Form + Strength	**TDBC-NIX PLUS ORAL Powder**
	Composition	Each Kg contains. Doxycycline HCl ….. 400 gm Tylosin Tartrate …….200 gm Colistin Sulphate…… 500MIU Bromhexine HCl ……..10gm
	Tracking ID/Date of submission & fee	Tracking ID: 7YR-X6T-QUM4 dated 20-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**Broxtin 24 Oral Powder of M/s Leads (Reg. # 088045)**
	GMP status	New DML issued on 26-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
3.	**Name and address of manufacturer**	**M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2,**

	/ Applicant	**National industrial zone, RCCI Estate Rawat- Islamabad**
	Brand Name +Dosage Form + Strength	**TDBC-NIX ORAL Powder**
	Composition	Each 100gm contains. Doxycycline HCl ….. 40 gm Tylosin Tartrate …….20 gm Colistin Sulphate…… 10gm Bromhexine HCl ……..2gm
	Tracking ID/Date of submission & fee	Tracking ID: Z4P-N3R-PQTN dated 20-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**Grand TD Oral Powder of M/s Grand pharma (Reg. # 103938)**
	GMP status	New DML issued on 26-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
4.	**Name and address of manufacturer / Applicant**	**M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad**
	Brand Name +Dosage Form + Strength	**NIX GOLD Oral Powder**
	Composition	Each Kg contains. Vitamin A……. 0.8 gm Vitamin D3 …… 0.16 gm Vitamin E……. 0.38 gm Vitamin B1 ……... 1.0 gm Vitamin B2 ……...1.25 gm Vitamin B12 ……. 0.001 gm Vitamin B3 …….. 6.25 gm Copper sulphate …….. 0.25 gm Magnesium sulphate …… 25.0 gm Calcium chloride …….. 0.023 gm Manganese sulphate …… 10.0 gm Potassium Iodide ……. 0.5 gm Sodium selenite …….. 0.01 gm DCP ……. 150.0 gm Sodium chloride …… 120.0gm Vitamin B6 …….. 4 gm Zinc sulphate …… 2.17gm
	Tracking ID/Date of submission & fee	Tracking ID: Z4P-N3R-PQTN dated 20-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Multivitamins & Minerals
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**White Gold Water Soluble Powder of M/s Leads pharma (Reg. # 058842)**
	GMP status	New DML issued on 26-01-2024.

	Remarks of the Evaluator.	
	Decision: Approved.	
5.	**Name and address of manufacturer / Applicant**	**M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad**
	Brand Name +Dosage Form + Strength	**ACO NIX-40 Oral Powder**
	Composition	Each 1000 gram contains Lincomycin as HCl …….. 400 gm
	Tracking ID/Date of submission & fee	Tracking ID: A7E-R4D-Q5GM dated 19-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & demanded price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**Aclinco 40% Water Soluble Powder of M/s ACME PHARMACEUTICALS (Reg. # 116957)**
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
6.	**Name and address of manufacturer / Applicant**	**M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad**
	Brand Name +Dosage Form + Strength	**ACO NIX-11 Oral Powder**
	Composition	Each 1000 gram contains Lincomycin as HCl …….. 110gm
	Tracking ID/Date of submission & fee	Tracking ID: XH6-5SX-3XJJ dated 19-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & demanded price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**Aclinco 11% Water Soluble Powder (Reg. # 116956)**
	GMP status	New DML issued on 26-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
7.	**Name and address of manufacturer / Applicant**	**M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad**
	Brand Name +Dosage Form + Strength	**NEO NIX- 72 Oral Powder**
	Composition	Each 1000 gram contains Neomycin Sulphate ……. 720 gm
	Tracking ID/Date of submission & fee	Tracking ID: 14M-NSA-N7HN dated 19-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications.
	Pack size & demanded price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Approval status of product in Reference Regulatory Authorities.	

	Me-too status	**Highneo 72% Oral Powder (Reg. # 116970)**
	GMP status	New DML issued on 26-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
8.	**Name and address of manufacturer / Applicant**	**M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad**
	Brand Name +Dosage Form + Strength	**NEO NIX- 60 Oral Powder**
	Composition	Each 1000 gram contains Neomycin Sulphate…… 60 gm
	Tracking ID/Date of submission & fee	Tracking ID: PJ2-VNE-PJ88 dated 19-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications.
	Pack size & demanded price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**Highneo 60% Oral Powder (Reg. # 116968)**
	GMP status	New DML issued on 26-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
9.	**Name and address of manufacturer / Applicant**	**M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad**
	Brand Name +Dosage Form + Strength	**OFLO NIX Oral Powder**
	Composition	Each gram contains: Oxytetracycline HCl ……. 150 mg Florfenicol ……. 150 mg
	Tracking ID/Date of submission & fee	Tracking ID: 7YE-W7M-9TDL dated 19-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications.
	Pack size & demanded price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**Florotet 15/15 Water Soluble Powder (Reg. # 117044)**
	GMP status	New DML issued on 26-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
10.	**Name and address of manufacturer / Applicant**	**M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad**
	Brand Name +Dosage Form + Strength	**OFLO NIX SUPER Oral Powder**
	Composition	Each gram contains: Oxytetracycline HCl …… 300 mg Florfenicol ……. 300 mg
	Tracking ID/Date of submission & fee	Tracking ID: P91-HW8-9YNN dated 14-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications.

	Pack size & demanded price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**Florotet 30/30 Oral Powder (Reg. # 117045)**
	GMP status	New DML issued on 26-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
11.	**Name and address of manufacturer / Applicant**	**M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad**
	Brand Name +Dosage Form + Strength	**COLI-48 Oral Powder**
	Composition	Each gram contains: Colistin Sulphate……. 4.8 MIU
	Tracking ID/Date of submission & fee	Tracking ID: 44Q-MZA-NEJY dated 14-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications.
	Pack size & demanded price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**Acme Col -48 Water Soluble Powder (Reg. # 116965)**
	GMP status	New DML issued on 26-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
12.	**Name and address of manufacturer / Applicant**	**M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad**
	Brand Name +Dosage Form + Strength	**COLI-6 Oral Powder**
	Composition	Each Gram Contains: Colistin Sulphate …… 6 MIU
	Tracking ID/Date of submission & fee	Tracking ID: ZQG-TTS-361J dated 14-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications.
	Pack size & demanded price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**Acme Col -60 Water Soluble Powder (Reg. # 116967)**
	GMP status	New DML issued on 26-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
13.	**Name and address of manufacturer / Applicant**	**M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad**
	Brand Name +Dosage Form + Strength	**V.VIT NIX Oral Powder**
	Composition	Each gram contains: Vitamin E……..…..…..5mg Vitamin B3……..…...…2mg L lysine…….....25mg DL methionine…….....…50mg Choline chloride……...100mg

		Virginiamycin……..…....12mg
	Tracking ID/Date of submission & fee	Tracking ID: E2N-YXL-V5BQ dated 14-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Multivitamin/Minerals
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications.
	Pack size & demanded price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**Virgocine Water Soluble Powder (Reg. # 117048)**
	GMP status	New DML issued on 26-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
14.	**Name and address of manufacturer / Applicant**	**M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad**
	Brand Name +Dosage Form + Strength	**CNO SUPER Oral Powder**
	Composition	Each gram contains: Oxytetracycline HCl …… 300mg Neomycin Sulphate …… 250mg Colistin Sulphate …… 0.5MIU
	Tracking ID/Date of submission & fee	Tracking ID: BH4-REM-6NT6 dated 13-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications.
	Pack size & demanded price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**Acme NOC 30/25/0.5 Water Soluble Powder (Reg. # 117041)**
	GMP status	New DML issued on 26-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
15.	**Name and address of manufacturer / Applicant**	**M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad**
	Brand Name +Dosage Form + Strength	**CNO COLI PLUS Oral Powder**
	Composition	Each gram contains: Oxytetracycline HCl …….. 200mg Neomycin Sulphate …… 200mg Colistin Sulphate ……. 0.55MIU
	Tracking ID/Date of submission & fee	Tracking ID: 2Z7-MP4-WH2Z dated 13-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications.
	Pack size & demanded price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**Acme NOC 20/20/0.55 Water Soluble Powder (Reg. # 117040)**
	GMP status	New DML issued on 26-01-2024.

	Remarks of the Evaluator.	
	Decision: Approved.	

Central Licensing Board in its 295th meeting held on 11th January 2024 approved the grant of DML (afresh) No. 000449 (by way of formulation) for Veterinary drug products to M/s Hirra Pharmaceutical Laboratories (Private) Limited located at 1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore, with following sections: -

i. Oral Powder Section (General / antibiotics) – Veterinary
ii. Oral Liquid Section (General / Antibiotics) – Veterinary

Authority in its 178th meeting held on 23rd January 2024, keeping in view of the decision taken in the past, acceded to the request of M/s Hirra Pharmaceuticals Laboratories, Lahore for Out-of-queue consideration of submitted applications of registrations of those drugs which were already registered with the firm before cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time and Grant of same registration numbers and brand names. Accordingly, previously registered products were considered in 334th meeting of Registration Board.

Now firm has submitted following applications against the grant of DML.

i. Oral Powder Section (General / antibiotics) – Veterinary		
16.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited 1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**HIRRA-AMPRO-98 Oral Water Soluble Powder**
	Composition	Each gm contains: Amprolium HCl--------980mg
	Tracking ID/Date of submission & fee	Tracking ID: 2HE-2ZR-TWBA dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & demanded price	1000gm, 500gm, 100gm, 50gm.
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	COCSTER-98 ORAL WATER SOLUBLE POWDER of M/s AAMSTER LABORATORIES (Reg. # 101990)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
17.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited 1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**Hirra-Doxy.T.D.C.B powder**
	Composition	Each 100gm contains: Doxycycline HCl ……. 20gm Tylosin tartrate ……. 10gm Bromohexine …….0.4gm Colistin sulphate ……..45MIU
	Tracking ID/Date of submission & fee	Tracking ID: TZE-ETU-ESRS dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotic, Mucolytic, Expectorant
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	1000gm, 500gm, 100gm, 50gm.

	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	SEPTIREX ORAL POWDER of M/s RAS PHARMACEUTICALS(PVT)LTD (Reg. # 097957)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
18.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**HIRRA-LINCOSPEC PLUS POWDER**
	Composition	Each Gram contains: Lincomycin as HCl----------33.3%w/w Spectinomycin as sulphate--------66.7%w/w
	Tracking ID/Date of submission & fee	Tracking ID: HXP-R1H-U8BJ dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	100g, 250g, 500g, 1kg, 5kg,10kg, 25kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	LINCOTIN POWDER. of M/s Selmore PHARMACEUTICALS (PVT)LTD (Reg. # 049618)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
19.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**HIRRA-LINCOSPEC ORAL POWDER**
	Composition	Each Gram contains: Lincomycin as HCl ---------- 222mg Spectinomycin as HCl -------- 444.67mg
	Tracking ID/Date of submission & fee	Tracking ID: RH6-PDP-GZ9J dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	100g, 250g, 500g, 1kg, 5kg,10kg, 25kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	PSL-100 WATER SOLUBLE POWDER, M/S. POULVET PHARMACEUTICALS (PVT) (Reg. # 118504)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
20.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form +	**HIRRA-LINCOCYN-44% Oral powder**

	Strength	
	Composition	Each 100 Gram contains: Lincomycin HCl Monohydrate…….44gm
	Tracking ID/Date of submission & fee	Tracking ID: XLV-ZAP-683Y dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	100g, 250g, 500g, 1kg, 5kg,10kg, 25kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Linc- HANS 44% Powder of M/s D-HAANS PHARMACEUTICALS (Reg. # 102214)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
21.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**HIRRA-LINCOCYN-11% Oral powder**
	Composition	Each 100 Gram contains: Lincomycin HCl Monohydrate…….11gm
	Tracking ID/Date of submission & fee	Tracking ID: XLV-ZAP-683Y dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	100g, 250g, 500g, 1kg, 5kg,10kg, 25kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Linc- HANS 11% Powder of M/s D-HAANS PHARMACEUTICALS (Reg. # 102212)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
22.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**HIRRA-LINCOCOL ORAL POWDER**
	Composition	Each 100Gram contains: Lincomycin as HCl----------10gm Colistin sulphate----------80MIU
	Tracking ID/Date of submission & fee	Tracking ID: P3L-TJY-WVZV dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	100g, 250g, 500g, 1kg, 5kg,10kg, 25kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**LIN KAWI Oral Powder of M/S.INSHAL PHARMACEUTICAL INDUSTRIES** (Reg. # 103843)

	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
23.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**HIRRA-HEXA FLUSH WATER SOLUBLE POWDER**
	Composition	Each gm Contains: Hexamethylene tetramine . . . . …… 955mg Vitamin B2 . . . . . 10mg Calcium pantothenate. . . . . … 5mg Nicotinamide……..25mg
	Tracking ID/Date of submission & fee	Tracking ID: PBW-LVB-J2UQ dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antinfective, Vitamin
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	100gm ,500gm,1000gm
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**FILTRAX WATER SOLUBLE POWDER of M/s PRIX Pharmaceutical** (Reg. # 043289)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
24.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**Hirra-Doxy.T.C.B-300 powder**
	Composition	Each 1000gm contains: Doxycycline HCl . . . . . 200gm Tylosin tartrate . . . . . 100gm Bromohexine . . . . . .05gm Colistin sulphate 480MIU
	Tracking ID/Date of submission & fee	Tracking ID: BWY-R8Z-RAWT dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotic, Mucolytic, Expectorant
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	50gm, 100gm ,500gm,1000gm
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	DOXIBAR-300 POWDER **of M/s WIMITS Pharmaceutical** (Reg. # 099289)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
25.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form +	**Hirra-Doxy T.60 Oral Water Soluble Powder**

	Strength	
	Composition	Each 100gm contains: Doxycycline HCl…….40g Tylosin tartrate……....20g
	Tracking ID/Date of submission & fee	Tracking ID: MUQ-99L-SM35 dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	50gm, 100gm ,500gm,1000gm
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**EDOTOX-60 ORAL WATER of M/s D-MAARSON PHARMACEUTICALS,** (Reg. # 099042)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
26.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**Hirra-Colistine Oral Powder**
	Composition	Each Kg contains Colistin sulphate----------500MIU
	Tracking ID/Date of submission & fee	Tracking ID: E6U-AMP-X8RE dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**CLOSUL-5 ORAL POWDER, M/S.APTLY PHARMACEUTICALS,** (Reg. # 093869)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	Referred me too productcontains Colistin sulphate 5MIU per Kg
	Decision: Approved with following composition: **"Each Kg contains** **Colistin sulphate----------5MIU"** **Firm shall submit fee of Rs. 30,000/- for correction in formulation, prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
27.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**Hirra-Amantadine 10% Powder**
	Composition	Each 100gm contains: Amantadine HCl--------10gm
	Tracking ID/Date of submission & fee	Tracking ID: T7G-UYT-NYW3 dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications

	Pack size & demanded price	50gm, 100gm ,500gm,1000gm
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**AMSTERDINE-1 ORAL WATER SOLUBLE POWDER of M/s AAMSTER LABORATORIES** (Reg. # 101996)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
28.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**Hirra Dox 80% Powder**
	Composition	Each gm contains: Doxycycline HCl …… 800mg
	Tracking ID/Date of submission & fee	Tracking ID: YUM-Y9D-LAH6 dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	50gm, 100gm ,500gm,1000gm
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**Hansydox 80% Powder, M/s Dot D-Hans Pharmaceuticals** (Reg. # 103953)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
ii. Oral Liquid Section (General / Antibiotics) – Veterinary		
29.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**HIRRA-ENRO-10% ORAL SOLUTION**
	Composition	Each ml contains: Enrofloxacin 100mg
	Tracking ID/Date of submission & fee	Tracking ID: 8QD-41W-1WHR dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	500ml, 1000ml
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**APSALIQ POLISTAR-100 ORAL SOLUTION, of M/s AL-HAMD POULTRY&LIVESTOCK SERVICES** (Reg. # 094399)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
30.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**

		(DML # 000449)
	Brand Name +Dosage Form + Strength	**Hirra-Tilcos 25% Oral Solution**
	Composition	Each ml contains Tilmicosin Phosphate---------250mg
	Tracking ID/Date of submission & fee	Tracking ID: 9T6-VBL-RNXX dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	100ml,150ml, 250ml,500ml, 1000ml, 2500ml
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**APOTIL ORAL SOLUTION, M/S.MYLAB(PVT)LTD** (Reg. # 097932)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
31.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**Hirra-Suppliment Oral Solution**
	Composition	Each ml contains Calcium-Chloride-Hexahydrate----------2mg Magnesium-Chloride Hexahydrate ----------4mg Potassium-Chloride----------8mg Sodium-Chloride----------120mg Cyanocobalamin----------0.025mg Sodium-Lactate----------42.7mg
	Tracking ID/Date of submission & fee	Tracking ID: QGG-HYT-SNPS dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	500ml, 1000ml
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**SUPPLITOL ORAL SOLUTION, M/S.ICI PAKISTAN LIMITED,LIFE SCIENCES** (Reg. # 099376)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
32.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**Hirra-S.Nor.C Oral Liquid**
	Composition	Each 100ml contains: Norfloxacin . . . . . 20gm Colistin Sulphate. 60MIU
	Tracking ID/Date of submission & fee	Tracking ID: EW4-EPE-15TD dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	500ml, 1000ml
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**COLI-NOR LIQUID, M/S LEADS PHARMA** (Reg. # 049501)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
33.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**Hirra Oxyfenda Gold Oral Liquid**
	Composition	Each ml Contains: Oxyclozanide . . . . . 62mg Oxfendazole……22.65mg Selenium……0.5mg Cobalt as sulphate…….1.67mg
	Tracking ID/Date of submission & fee	Tracking ID: UPL-X82-9J1A dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	100ml,200ml,500ml, 1000ml
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**CLOZANEW PLUS DRENCH, M/S A&K PHARMACEUTICALS** (Reg. # 044946)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
34.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**Hirra-Enro+col 25% Oral Liquid**
	Composition	Each 1000ml contains: Enrofloxacin . . . . . 250gm Colistin Sulphate. 50MIU
	Tracking ID/Date of submission & fee	Tracking ID: T41-RP6-QTUR dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	500ml, 1000ml
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**EFLIN-DA-25% ORAL LIQUID, M/S.VETEC LABORATORIES** (Reg. # 099306)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	

35.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**Hirra-Flore 23% Oral Liquid**
	Composition	Each 100ml contains: Florfenicol . . . . . 23gm Colistin Sulphate. 50MIU
	Tracking ID/Date of submission & fee	Tracking ID: LXW-5SS-NTMT dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	500ml, 1000ml
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**LORSTRIN-23 ORAL LIQUID, M/S.AAMSTER LABORATORIES** (Reg. # 101425)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
36.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**Hirra-Florecol Oral Liquid**
	Composition	Each 100ml contains: Florfenicol . . . . . 11gm Colistin Sulphate. 50MIU
	Tracking ID/Date of submission & fee	Tracking ID: 4G7-21B-5M6H dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	500ml, 1000ml
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**LORSTRIN-11 ORAL LIQUID, M/S.AAMSTER LABORATORIES** (Reg. # 099482)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
37.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**HIRRA-ALBENDA 15% ORAL SUSPENSION**
	Composition	Each ml contains: Albendazole 150mg
	Tracking ID/Date of submission & fee	Tracking ID: PUA-B3R-ATVB dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & demanded price	500ml, 1000ml
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**BEN ROLD 15% ORAL SUSPENSION, M/S.HAAROLDS PHARMACEUTICALS(PVT) LTD** (Reg. # 109074)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
38.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**Hirra-Bvendaclose Plus Oral Suspension**
	Composition	Each ml contains: Albendazole . . . . . 100mg Closantel……..20mg
	Tracking ID/Date of submission & fee	Tracking ID: Q68-E6Y-RBY3 dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	500ml, 1000ml
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**BENDA SANTEL 10% ORAL SUSPENSION, M/S.KAYANS PHARMACEUTICALS,** (Reg. # 111362
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
39.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)**
	Brand Name +Dosage Form + Strength	**Hirra-Abizole Plus Drench**
	Composition	Each ml contains: Albendazole 112.5mg
	Tracking ID/Date of submission & fee	Tracking ID: MV5-VVB-QBSM dated 04-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	500ml, 1000ml
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**ALVAZINE DRENCH, M/S.MYLAB(PVT)LTD,** (Reg. # 101455)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	
40.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**

		(DML # 000449)
	Brand Name +Dosage Form + Strength	**HIRRA MULTI RS SOLUTION**
	Composition	Each ml Contains: Sulphadiazine ----------35.500mg Sulphadimidine ----------28.400mg Neomycin Sulphate---------1.800mg Hyoscine Methylbromide------- 0.040mg Pectin---------- 7.100mg Kaolin----------103.300mg Vitamin B1----------0.150mg Vitamin B2----------0.220mg
	Tracking ID/Date of submission & fee	Tracking ID: AD-1ME-5A6D dated 22-04-2024, Rs. 30,000/- 27-03-2024
	Pharmacological Group	Antibiotic/Vitamin
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's specifications
	Pack size & demanded price	100ml, 250ml, 500ml, 1000ml
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	**SCOUR-X, M/s. SELMORE PHARMACEUTICALS (PVT) LTD,** (Reg. # 029661)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	

Case no. 02 Registration applications for local manufacturing of (Human) drugs on Form 5F.

41.	Name, address of Applicant / Marketing Authorization Holder	**M/s Nagarsons Pharmaceuticals.** **Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy.No 8861 dated 18-03-2021
	Details of fee submitted	Rs.50,000/- dated 12-02-2021
	The proposed proprietary name / brand name	**Darrel IV 2.25gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin as sodium……2g Tazobactam as sodium …….0.25g
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Piperacillin and tazobactam Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows: Applicant firm: M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat. Manufacturer firm: M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad Brand Name: PIPRABEN Injection 2.25g Injection	
	Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	

42.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad-Pakistan**
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 17-12-2020 based on inspection conducted on 09-11-2020. The firm has submitted application for the renewal of GMP on 10-11-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 15-12-2014 specifying Tablet (General) section.

	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 25241 dated 06-09-2022 Rs.75,000/- dated 18-03-2022
	The proposed proprietary name / brand name	**Ertusit Tablets 15mg/100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ertugliflozin L-pyroglutamic eq.to Ertugliflozin ……. 15mg Sitagliptin phosphate monohydrate eq.to Sitagliptin …… 100mg
	Pharmacotherapeutic Group of (API)	**Ertugliflozin:** Anti-Diabetic **Sitagliptin:** Anti-Diabetic
	Pharmaceutical form of applied drug	Film coated tablets.
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	7's, 10's, 14's, 20's, 28's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Steglujan Tablets 5/100mg (FDA Approved)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	**Ertugliflozin:** **Name:** Chifeng Arker Pharmaceutical Technology Co., Ltd. **Address:** No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China **Sitagliptin:** **Name:** Zhejiang Yongtai Pharmaceutical Co., Ltd **Address:** No. 1, 4th Donghai Avenue, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance of both API's separately.
	Stability Studies of Drug Substance (Conditions & duration of	**Ertugliflozin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The

	Stability studies)	accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. **Sitagliptin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 18 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Steglujan Tablets 15/100mg manufactured by Merck & Co., Inc. Firm has submitted CDP results of their product against the innovator's product Steglujan Tablets 15/100mg in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Ertugliflozin L-pyroglutamic acid:** **Name:** Chifeng Arker Pharmaceutical Technology Co., Ltd. **Address:** No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China. **Sitagliptin Phosphate Monohydrate:** **Name:** Zhejiang Yongtai Pharmaceutical Co., Ltd **Address:** No. 1, 4th Donghai Avenue, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China.		
API Lot No.	**Ertugliflozin:** D84-2001101 **Sitagliptin:** 1827-001-20048		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T01	T02	T03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	21-06-2021	21-06-2021	21-06-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Previous approval of applications with stability study data of our product Tanavul Tablets 10mg which was approved in 320th meeting of Registration Board. The report confirms following points: i. The HPLC software is 21CFR compliant. ii. Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin:** Firm has submitted copy of GMP Certificate (No. NM20150062) dated 29-12-2015 issued by state food and drug administration. **Sitagliptin:** Firm has submitted copy of GMP Certificate dated 29-06-2021 issued by Medical and Chemical Industry Association. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin:** Firm has submitted copy of commercial invoice cleared on 17-03-2021 specifying 200g of Ertugliflozin L-pyroglutamic acid. The invoice is cleared by AD (I&E) DRAP, Islamabad. **Sitagliptin:** Firm has submitted copy of commercial invoice cleared on 01-09-2023 specifying 100kg of Sitagliptin Phosphate Monohydrate. The invoice is cleared by AD (I&E) DRAP, Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

43.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Caraway Pharmaceuticals Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on basis of inspection conducted on 09-03-2020

	Evidence of approval of manufacturing facility	GMP certificate issued on basis of inspection conducted on 09-03-2020 declares availability of Tablet general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 24077 dated 25-08-2022 Rs.30,000/- dated 23-08-2022
	The proposed proprietary name / brand name	**Terb-C 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Terbinafine HCl …..250mg
	Pharmaceutical form of applied drug	Uncoated tablet
	Pharmacotherapeutic Group of (API)	Anti fungal agent
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lamisil tablet Approved by US FDA
	For generic drugs (me-too status)	Lamisil tablet of Novartis Reg. 013209
	Name and address of API manufacturer.	M/s Saptagir Laboratories Pvt Ltd Sy.no parts of 27, 46 & 50 to 56, Ananthasagar (Vill) chegunta (Mandal), Medak (Dist.), Telanga, India-502 247
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH and the real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures,

		validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies against the Lamisil tablet of M/s Novartis has been submitted
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions.

STABILITY STUDY DATA			
Manufacturer of API	M/s Saptagir Laboratories Pvt Ltd Sy.no parts of 27, 46 & 50 to 56, Ananthasagar (Vill) chegunta (Mandal), Medak (Dist.), Telanga, India-502 247		
API Lot No.	TH0020121		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 3, 6 (Months)		
Batch No.	TE250T004	TE250T005	TE250T005 TE250T006
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	05-2021	05-2021	05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Section #	Observations	Firm's response
1.3	Latest GMP inspection report of the drug product manufacturer shall be submitted, conducted within last three years.	
1.5.2	Label claim for strength of Terbinafine shall be submitted as per Innovator drug product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
3.2.S.4.4	Submit COA of Terbinafine HCl of relevant batch used for manufacturing of drug product stability batches, from the drug substance manufacturer & drug product manufacturer.	
3.2.P.2.2.1	Submit CDP studies in three dissolution mediums of pH 1.2, 4.5 & 6.8 performed against the reference product.	
3.2.S.7	• Long term stability studies data for Empagliflozin shall be submitted till claimed shelf life. • Long term stability studies data as per Zone IV conditions shall be submitted for Linagliptin.	
3.2.P.8.3	Submit following: • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import). • Data of stability batches supported by respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

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

44.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore Plot #129 Sundar Industrial Estate,Raiwind road,Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 08-09-21 based on inspection conducted on Dated 14-11-23 (GMP Certificate No.188/2023-DRAP(AD-3489860170))

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 07-02-2014 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 27749 dated 30-09-2022, Rs.30,000/- dated 23-09-2022
	Details of fee submitted	PKR 30,000/- Dated 23-09-2022
	The proposed proprietary name / brand name	**Limpa 25mg/5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Film Coated tablet contains:** Empagliflozin …… 25mg Linagliptin …..……..…… 5mg
	Pharmacotherapeutic Group of (API)	Empagliflozin: Oral hypoglycemic agent Linagliptin: Dipeptidyl peptidase-4 (DPP-4) inhibitors
	Pharmaceutical form of applied drug	Almost White coloured, Oblong scored film coated tablet
	Reference to Finished product specifications	Innovator specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Glyxambi 25mg/5mg tablet by M/s Boehringer Ingelheim (USFDA Approved)
	For generic drugs (me-too status)	Diampa LT 25mg/5mg Tablet of M/s Getz Pharma **Registration number**: 112532
	Name and address of API manufacturer.	**Empagliflozin:** M/s Zhejiang Hongyuan Pharmaceutical Co.,Ltd Chem&APIs Industrial Zone, Zhejiang China,317016 **Linagliptin:** **M/s Lee Pharma Limited,** Survey no: 257& 258/1, Door no: 11-6/56, C-Block, Opp.: IDPL Factory, Moosapet Balanagar (Post), Hyderabad – 500 037, Telangana State, INDIA.
	Module-II (Quality Overall Summary)	The Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Linagliptin:**

		Real time: 30°C ± 2°C / 65% ± 5%RH for 60months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against Glyxambi 25mg/5mg tablet M/s Boehringer Ingelheim CDP has been performed against the same brand that is Glyxambi 10mg/5mg tablet of M/s Boehringer Ingelheim in Acidic media (pH-1.2), Acetate Buffer (pH-4.5) & Phosphate Buffer (pH 6.8). The values for are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including accuracy, precision and specificity.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** M/s Zhejiang Hongyuan Pharmaceutical Co.,Ltd Chem&APIs Industrial Zone, Zhejiang China,317016 **Linagliptin:** **M/s Lee Pharma Limited,** Survey no: 257& 258/1, Door no: 11-6/56, C-Block, Opp.: IDPL Factory, Moosapet Balanagar (Post), Hyderabad – 500 037, Telangana State, INDIA.		
API Lot No.	For Empagliflozin: B#**EPG20220303** For Linagliptin: B# **LIF22008**		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 3, 6 (Months)		
Batch No.	THL001	THL002	THL003
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	19-06-2022	20-06-2022	21-06-2022
No. of Batches	03		

45.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 08-09-21 based on inspection conducted on Dated 14-11-23

		(GMP Certificate No.188/2023-DRAP(AD-3489860170))
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 07-02-2014 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 27748 dated 30-09-2022 Rs.30,000/- dated 23-09-2022
	The proposed proprietary name / brand name	**Limpa 10mg/5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Empagliflozin ……... 10mg Linagliptin …...…… 5mg
	Pharmacotherapeutic Group of (API)	Empagliflozin: Oral hypoglycemic agent Linagliptin: Dipeptidyl peptidase-4 (DPP-4) inhibitors
	Pharmaceutical form of applied drug	Almost White coloured, Oblong scored film coated tablet
	Reference to Finished product specifications	Innovator specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Glyxambi 10mg/5mg tablet by M/s Boehringer Ingelheim (USFDA Approved)
	For generic drugs (me-too status)	Diampa LT 10mg/5mg Tablet of M/s Getz Pharma Registration number: 122552
	Name and address of API manufacturer.	**Empagliflozin:** M/s Zhejiang Hongyuan Pharmaceutical Co.,Ltd Chem&APIs Industrial Zone, Zhejiang China,317016 **Linagliptin:** **M/s Lee Pharma Limited,** Survey no: 257& 258/1, Door no: 11-6/56, C-Block, Opp.: IDPL Factory, Moosapet Balanagar (Post), Hyderabad – 500 037, Telangana State, INDIA.
	Module-II (Quality Overall Summary)	The Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months

		Linagliptin: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against Glyxambi 10mg/5mg tablet M/s Boehringer Ingelheim CDP has been performed against the same brand that is Glyxambi 10mg/5mg tablet of M/s Boehringer Ingelheim in Acidic media (pH-1.2), Acetate Buffer (pH-4.5) & Phosphate Buffer (pH 6.8). The values for are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including accuracy, precision and specificity.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** M/s Zhejiang Hongyuan Pharmaceutical Co.,Ltd Chem&APIs Industrial Zone, Zhejiang China,317016 **Linagliptin:** **M/s Lee Pharma Limited,** Survey no: 257& 258/1, Door no: 11-6/56, C-Block, Opp.: IDPL Factory, Moosapet Balanagar (Post), Hyderabad – 500 037, Telangana State, INDIA.		
API Lot No.	For Empagliflozin: B#**EPG20220303** For Linagliptin: B# **LIF22008**		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 3, 6 (Months)		
Batch No.	THE001	THE002	THE003
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	16-06-2022	17-06-2022	18-06-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**For Empagliflozin** Firm has submitted copy of DML (Zhe20090508) in name of Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang, China issued by Zhejiang Food and Drug Administration **For Linagliptin**

		Copy of GMP certificate issued by Drug control Administration Government of Telangana valid till 20/05/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**For Empagliflozin** • Copy of Form 6 Computerized No. K-395982883974 dated 12 -05-22 is submitted wherein the permission to import Empagliflozin (270gm) for the purpose of test/analysis and stability studies is granted. **For Linagliptin** • Copy of Form 6 Computerized No.K-539382885187 dated 09-06-22 is submitted wherein the permission to import Linagliptin for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Section #	Observations	Firm's response
3.2.S.4.2	Justification shall be submitted for different chromatographic conditions for Assay test of Empagliflozin and Linagliptin, mentioned in the submitted analytical procedure of drug substance manufacturer and drug product manufacturer.	Firm has submitted revised analytical procedures for both drug substances.
3.2.S.7	• Long term stability studies data for Empagliflozin shall be submitted till claimed shelf life. • Long term stability studies data as per Zone IV conditions shall be submitted for Linagliptin.	Submitted.

Decision: Registration Board approved the applications of Limpa 10mg/5mg Tablet & Limpa 25mg/5mg.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

46.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-Mark Pharmaceuticals (Pvt.) Ltd, Plot No. 527, Sundar Industrial Estate, Lahore, Pakistan.**
	Name, address of Manufacturing site.	M/s Bio-Mark Pharmaceuticals (Pvt.) Ltd, Plot No. 527, Sundar Industrial Estate, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Copy of GMP certificate No. 47/2020-DRAP (AD- 849966-789 dated 26-02-2020 issued on the basis of inspection conducted on 13-02-2020.
	Evidence of approval of manufacturing facility	Copy of GMP certificate No. 47/2020-DRAP (AD- 849966-789 dated 26-02-2020 issued on the basis of inspection conducted on 13-02-2020 declares availability of Tablet General Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 23372 dated 18-08-2022 Rs.30,000/- dated 28-02-2022
	The proposed proprietary name / brand name	**Empamet tablet 5/500 tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…….5 mg Metformin HCl …..500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic combination
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy by Boehringer Ingelheim Pharmaceuticals, Inc. is USFDA Approved.
	For generic drugs (me-too status)	Diampa-M 5/500 of M/s Getz pharma
	Name and address of API manufacturer.	**Metformin Hydrochloride** M/s Aarti Drugs Limited, Plot no. 109-D, Mahendra Industrial Estate Road no. 29, Sion (East) Mumbai, India. **Empagliflozin** M/s Lianyunganng Jari Pharmaceuticals Co., Ltd. No. 18 Zhenhua Road, Linyungang City, Jiangsu Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, 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)	Submitted for both drug substances as per Zone IV conditions
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the Diampa-M 5/500 of M/s Getz pharma along with CDP studies wherein values f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**Metformin Hydrochloride** Aarti Drugs Limited, Mahendra Industrial Estate Plot No.211-213, Road No.2, G.I.D.C, Sarigam District, Valsad, Gujarat, India **Empagliflozin** M/s Lianyunganng Jari Pharmaceuticals Co., Ltd. No. 18 Zhenhua Road, Linyungang City, Jiangsu Province, China.		
API Lot No.	Empagliflozin: WSO1 Metformin Hydrochloride: MEF/18071531		
Description of Pack (Container closure system)	Alu Alu. 2 (7's) Blisters with aluminum foil having leaflet and packed in unit carton of bleach board.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	22LEML001	22LEML002	22LEML003
Batch Size	2,000	2,000	2,000
Manufacturing Date	11/2021	11/2021	11/2021
Date of Initiation	24/11/2021	24/11/2021	24/11/2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP certificate No. JS20191190 issued by Jiangsu Drug Administration valid till 29/11/2024. **Metformin:** Copy of GMP certificate No. 23064344 issued by Food and Drug Administration Chandhinagar Gujarat state,India valid till 20-06-2026

3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Section #	Observations	Firm's response
3.2.P.8.3	Submit following: • Documents for the procurement of API with approval from DRAP (in case of import). • Complete batch manufacturing record pf stability batches shall be submitted.	Firm has submitted following: • Copy of commercial invoice no. 21YX0054L attested by AD I&E DRAP, Lahore dated 23-08-2021 for import of Empagliflozin (1Kg). • Copy of commercial invoice no. EXP/1577/20-21 attested by AD I&E DRAP, Lahore dated 01-10-2020 for import of Metformin HCl (1000Kg). • Batch manufacturing record for stability batches.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

47.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pinnacle Biotech Pvt. Ltd. Plot No. FD-49-A8 ,FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Pinnacle Biotech Pvt. Ltd. Plot No. FD-49-A8 ,FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate based on inspection conducted on 21-10-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 13-09-2021 specifying Capsule (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 23372 dated 18-08-2022 Rs.30,000/- dated 28-02-2022

	The proposed proprietary name / brand name	**Gerdmax 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Enteric Coated Pellets of Esomeprazole Magnesium Trihydrate Eq. to Esomeprazole…20mg
	Pharmacotherapeutic Group of (API)	Capsule
	Pharmaceutical form of applied drug	Proton pump inhibitor
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Nexum 20 mg cap of M/s Getz pharma (Reg.# 033891)
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance of both API's separately and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance of both API's separately.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Both accelerated & long-term stability studies from M/s Vision Pharma has been submitted for Esomeprazole EC 8.5% pellets as per Zone IVa conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Nexum capsule of M/s Getz. Firm has submitted CDP results of their product against the innovator's product Glyxambi Tablets 10mg/5mg in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan.		
API Lot No.	EMZ046605		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-185	T-190	T-191
Batch Size	1500 capsules	1500 capsules	1500 capsules
Manufacturing Date	03-2023	03-2023	03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DRAP on the basis of inspection conducted on 14-06-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 10-02-2023 specifying 20Kgs of Esomeprazole Magnesium EC pellets 8.5% from M/s Vision Pharmacueticals.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

Section #	Observations	Firm's response
3.2.S.4.1	Justify the limits of ± 10% for Assay test of Esomeprazole Magnesium EC pellets, while considering it as drug substance.	
3.2.P.1.2	Justify the proposed weight/capsule of Esomeprazole Mg 8.5% EC pellets against the label claim of 20mg Esomeprazole.	
3.2.P.2.2.1	Justification shall be submitted for not performing CDP and Pharmaceutical equivalence studies against the Innovator product.	
3.2.P.8.3	• Record of Digital data logger for temperature and humidity monitoring of stability	

		chambers (real time and accelerated) shall be submitted.	
	--	Complete batch manufacturing record pf stability batches shall be submitted.	
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings			
48.	**Name, address of Applicant / Marketing Authorization Holder**		**M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.		M/s Welwink Pharmaceuticals Factory G.T. Road, Industrial Estate, Gujranwala Cantt.
	Status of the applicant		☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm		--
	Evidence of approval of manufacturing facility		--
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted		Dy.No 25819 dated 13-09-2022
	The proposed proprietary name / brand name		**Empamet 25/1000 mg XR Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each Extended Releae Tablet Contains: Empagliflozin……25mg Metformin HCl……..1000mg
	Pharmacotherapeutic Group of (API)		Antidiabetic combination
	Pharmaceutical form of applied drug		Film coated tablet.
	Reference to Finished product specifications		Innovator's specifications.
	Proposed Pack size		As per SRO
	Proposed unit price		As per SRO
	The status in reference regulatory authorities		Trijardy by Boehringer Ingelheim Pharmaceuticals, Inc. is USFDA Approved.
	For generic drugs (me-too status)		Diampa-M 5/500 of M/s Getz pharma
	Name and address of API manufacturer.		**Metformin Hydrochloride** M/s Aarti Drugs Limited, Plot no. 211-213, Road no. 2, G.I.D.C., Sarigam Valsad, Gujarat India. **Empagliflozin** M/s Fuxin Long Rui Pharmaceutical Co, Ltd - China Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China1
	Module-II (Quality Overall Summary)		Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, 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)	Submitted for both drug substances as per Zone IV conditions
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the Diampa-M 12.55/500 of M/s Getz pharma along with CDP studies wherein values f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	**Metformin Hydrochloride** M/s Aarti Drugs Limited, Plot no. 211-213, Road no. 2, G.I.D.C., Sarigam Valsad, Gujarat India. **Empagliflozin** M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15, Donghai 5th Avenue, Zhejiang Provinceal Chemical and medical Rw Materials Base Linhai Zone, Taizhou City, Zhejiang province, China.		
API Lot No.	Metformin Hydrochloride: MEF/11020485		
Description of Pack (Container closure system)	Alu Alu Blisters with aluminum foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	EGMF-12.5/500/T001	EGMF-12.5/500/T002	EGMF-12.5/500/T003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	10/2021	11/2021	11/2021
No. of Batches	3		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Section #	Observations	Firm's response
1.1	Justify the validity of submitted application since the provided fee challan has not been paid as verified from online eDRAP - Portal	

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

49.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s Welwink Pharmaceuticals Factory G.T. Road, Industrial Estate, Gujranwala Cantt.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	--
	Evidence of approval of manufacturing facility	--
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 25818 dated 13-09-2022 Rs.30,000/- dated 24-12-2021
	The proposed proprietary name / brand name	**Empamet 10/1000 mg XR Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Releae Tablet Contains: Empagliflozin……10mg Metformin HCl……..1000mg
	Pharmacotherapeutic Group of (API)	Antidiabetic combination
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy by Boehringer Ingelheim Pharmaceuticals, Inc. is USFDA Approved.

	For generic drugs (me-too status)	Diampa-M 5/500 of M/s Getz pharma
	Name and address of API manufacturer.	**Metformin Hydrochloride** M/s Aarti Drugs Limited, Plot no. 211-213, Road no. 2, G.I.D.C., Sarigam Valsad, Gujarat India. **Empagliflozin** M/s Fuxin Long Rui Pharmaceutical Co, Ltd - China Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China1
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, 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)	Submitted for both drug substances as per Zone IV conditions
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	--
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	**Metformin Hydrochloride** M/s Aarti Drugs Limited, Plot no. 211-213, Road no. 2, G.I.D.C., Sarigam Valsad, Gujarat India. **Empagliflozin** M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15, Donghai 5th Avenue, Zhejiang Provinceal Chemical and medical Rw Materials Base Linhai Zone, Taizhou City, Zhejiang province, China.
API Lot No.	--

Description of Pack (Container closure system)	Alu Alu Blisters with aluminum foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T01	T02	T03
Batch Size	86 packs	86 packs	86 packs
Manufacturing Date	05-2020	05-2020	05-2020
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Section #	Observations	Firm's response
1.3	• Submit copy of valid DML of drug product manufacturer. • Submit copy of latest GMP inspection report conducted within last three years of drug product manufacturers.	
1.6.5	Submit valid DML/GMP certificate of drug substance manufacturers, issued by relevant regulatory authority of country of origin.	
3.2.S.1.3	Justify the declaration of solubility of Empagliflozin as "Practically insoluble in water" with reference to the innovator drug product literature	
3.2.S.4.1	• Drug substance specifications and analytical procedure shall be submitted from drug product manufacturer for Empagliflozin. • Drug substance specifications and analytical procedure shall be submitted from drug product manufacturer and drug substance manufacturer for Metformin HCl.	

3.2.S.4.3	Analytical method verification studies of drug substances shall be submitted from drug product manufacturer.	
3.2.S.4.4	COA of Metformin HCl submitted from drug product manufacturer declares results from M/s Weatherfolds.	
3.2.S.7.3	Long term stability studies data shall be submitted for Empagliflozin, till claimed shelf life as per Zone IV conditions.	
3.2.P.1	Different list of excipients is provided in section 3.2.P.1 & 3.2. P.2.1. Justification shall be submitted in this regard.	
3.2.P.2.2.1	Conflicting data for CDP studies has been submitted wherein different time points and f2 vakues have been reported among several summary sheets.	
3.2.P.5	Different time points for dissolution test of Metformin HCl have been submitted in drug product specifications and analytical procedure.	
3.2.P.5.4	Justification shall be submitted for selected dissolution time points for Metformin HCl against the literature of innovator drug product approved by US FDA.	
3.2.P.8.3	Submit following: • Documents for the procurement of API with approval from DRAP (in case of import). • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). • Complete bath manufacturing record, including details of dispensed quantitites and other activities.	

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

50.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate issued on the basis of inspection conducted on 04-02-2020.
	Evidence of approval of manufacturing facility	Copy of GMP certificate issued on the basis of inspection conducted on 04-02-2020 declares availability of Tablet General Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Dy. No. and date of submission & Details of fee submitted	Dy.No 23832 dated 23-08-2022 Rs.30,000/- dated 20-06-2022
	The proposed proprietary name / brand name	**Jargin Duo 12.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin HCl …..500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic combination
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy by Boehringer Ingelheim Pharmaceuticals, Inc. is USFDA Approved.
	For generic drugs (me-too status)	Diampa-M 5/500 of M/s Getz pharma
	Name and address of API manufacturer.	**Metformin Hydrochloride** M/s Aarti Drugs Limited, Plot no. 211-213, Road no. 2, G.I.D.C., Sarigam Valsad, Gujarat India. **Empagliflozin** M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15, Donghai 5th Avenue, Zhejiang Provinceal Chemical and medical Rw Materials Base Linhai Zone, Taizhou City, Zhejiang province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, 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)	Submitted for both drug substances as per Zone IV conditions
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the Diampa-M 12.55/500 of M/s Getz pharma along with CDP studies wherein values f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	**Metformin Hydrochloride** M/s Aarti Drugs Limited, Plot no. 211-213, Road no. 2, G.I.D.C., Sarigam Valsad, Gujarat India. **Empagliflozin** M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15, Donghai 5th Avenue, Zhejiang Provinceal Chemical and medical Rw Materials Base Linhai Zone, Taizhou City, Zhejiang province, China.		
API Lot No.	Metformin Hydrochloride: MEF/11020485		
Description of Pack (Container closure system)	Alu Alu Blisters with aluminum foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	EGMF-12.5/500/T001	EGMF-12.5/500/T002	EGMF-12.5/500/T003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	10/2021	11/2021	11/2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Section #	**Observations**	**Firm's response**

1.6.5	Submit valid DML/GMP certificate of drug substance manufacturers, issued by relevant regulatory authority of country of origin.	
3.2.S.1.3	Justify the declaration of solubility of Empagliflozin as "Practically insoluble in water" with reference to the innovator drug product literature	
3.2.S.4.1	Justify the variation in drug substance specifications between drug substance manufacturer and M/s Pharmedic laboratories for Empagliflozin	
3.2.S.4.3	Analytical method verification studies of drug substances shall be submitted from M/s Pharmedic laboratories.	
3.2.S.4.4	• Submit COA of relevant batch of Metformin HCl & Empagliflozin used for preparation for drug product trial batches, from drug substance manufacturer. • Submitted COA of Empagliflozin form M./s Pharmedic Laboratories declare drug substance manufacturer as M/s Shanghai YST Pharma Co. Ltd, China whereas 3.2.S part has been submitted from M M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. Justification shall be submitted in this regard.	
3.2.S.7.3	Long term stability studies data of Empagliflozin shall be submitted till claimed shelf life as per Zone IV conditions.	
3.2.P.5.1	Justification shall be submitted for dissolution limits of 30 minutes with reference to the innovator drug product literature.	
3.2.P.5.4	Justification shall be submitted for not performing "Uniformity of Dosage Unit" test by way of "Content Uniformity" for Empagliflozin.	
3.2.P.8.3	Submit following: • Documents for the procurement of API with approval from DRAP (in case of import). • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

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

51.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate issued dated 23-11-2021

	Evidence of approval of manufacturing facility	Copy of GMP certificate issued dated 23-11-2021 confirms availability of Tablet General Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 22077 dated 03-08-2022 Rs.30,000/- dated 28-07-2022
	The proposed proprietary name / brand name	**Empazin M 12.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin …… 12.5mg Metformin HCl …… 500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic combination
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy by Boehringer Ingelheim Pharmaceuticals, Inc. is USFDA Approved.
	For generic drugs (me-too status)	Diampa-M 5/500 of M/s Getz pharma
	Name and address of API manufacturer.	**Metformin Hydrochloride** M/s Smruthi Organics ltd. Plot no. A-27, M.I.D.C Chincholi, Taluka Mohol Solapur Maharashtra, India **Empagliflozin** M/s Fuxin Long Rui Pharmaceutical Co, Ltd - China Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China1
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, 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)	Submitted for both drug substances as per Zone IV conditions

	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the Xenglu-Met tablet of M/s Hilton pharma along with CDP studies wherein values f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**Metformin Hydrochloride** M/s Smruthi Organics ltd. Plot no. A-27, M.I.D.C Chincholi, Taluka Mohol Solapur Maharashtra, India. **Empagliflozin** M/s Fuxin Long Rui Pharmaceutical Co, Ltd - China Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China1		
API Lot No.	Metformin Hydrochloride: MET/0334/21 Empagliflozin: E-20181027-D02-E06-01		
Description of Pack (Container closure system)	Alu Alu Blisters with aluminum foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T037	T038	T039
Batch Size	1200 tab	1200 tab	1200 tab
Manufacturing Date	21-09-2021	22-09-2021	23-09-2021
No. of Batches	3		

52.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate issued dated 23-11-2021
	Evidence of approval of manufacturing facility	Copy of GMP certificate issued dated 23-11-2021 confirms availability of Tablet General Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Dy. No. and date of submission & Details of fee submitted	Dy.No 22952 dated 15-08-2022 Rs.30,000/- dated 05-08-2022
	The proposed proprietary name / brand name	**Empazin M 5/850 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin …… 5mg Metformin HCl …… 850mg
	Pharmacotherapeutic Group of (API)	Antidiabetic combination
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy by Boehringer Ingelheim Pharmaceuticals, Inc. is USFDA Approved.
	For generic drugs (me-too status)	Diampa-M 5/500 of M/s Getz pharma
	Name and address of API manufacturer.	**Metformin Hydrochloride** M/s Smruthi Organics ltd. Plot no. A-27, M.I.D.C Chincholi, Taluka Mohol Solapur Maharashtra, India **Empagliflozin** M/s Fuxin Long Rui Pharmaceutical Co, Ltd - China Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China1
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, 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)	Submitted for both drug substances as per Zone IV conditions
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the Xenglu-Met tablet of M/s Hilton pharma along with CDP studies wherein values f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**Metformin Hydrochloride** M/s Smruthi Organics ltd. Plot no. A-27, M.I.D.C Chincholi, Taluka Mohol Solapur Maharashtra, India. **Empagliflozin** M/s Fuxin Long Rui Pharmaceutical Co, Ltd - China Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China1		
API Lot No.	Metformin Hydrochloride: MET/0334/21 Empagliflozin: E-20181027-D02-E06-01		
Description of Pack (Container closure system)	Alu Alu Blisters with aluminum foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T040	T041	T042
Batch Size	1200 tab	1200 tab	1200 tab
Manufacturing Date	12-10-2021	13-10-2021	14-10-2021
No. of Batches	3		

53.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate issued dated 23-11-2021
	Evidence of approval of manufacturing facility	Copy of GMP certificate issued dated 23-11-2021 confirms availability of Tablet General Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 22078 dated 03-08-2022 Rs.30,000/- dated 30-06-2022
	The proposed proprietary name / brand name	**Empazin M 5/500 mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin …… 5mg Metformin HCl …… 500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic combination
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy by Boehringer Ingelheim Pharmaceuticals, Inc. is USFDA Approved.
	For generic drugs (me-too status)	Diampa-M 5/500 of M/s Getz pharma
	Name and address of API manufacturer.	**Metformin Hydrochloride** M/s Smruthi Organics ltd. Plot no. A-27, M.I.D.C Chincholi, Taluka Mohol Solapur Maharashtra, India **Empagliflozin** M/s Fuxin Long Rui Pharmaceutical Co, Ltd - China Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China1
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, 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)	Submitted for both drug substances as per Zone IV conditions
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the Xenglu-Met tablet of M/s Hilton

		pharma along with CDP studies wherein values f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	**Metformin Hydrochloride** M/s Smruthi Organics ltd. Plot no. A-27, M.I.D.C Chincholi, Taluka Mohol Solapur Maharashtra, India. **Empagliflozin** M/s Fuxin Long Rui Pharmaceutical Co, Ltd - China Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China1		
API Lot No.	Metformin Hydrochloride: MET/0334/21 Empagliflozin: E-20181027-D02-E06-01		
Description of Pack (Container closure system)	Alu Alu Blisters with aluminum foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T034	T035	T036
Batch Size	1200 tab	1200 tab	1200 tab
Manufacturing Date	13-09-2021	14-09-2021	15-09-2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to PSI of its product Sofida tablet approved in 291st meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** DML no. Liao20150233 Valid till 17-11-2027. **Metformin:** Copy of GMP certificate issued by F&DA Maharashtra, India valid till 21-11-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted cpy of commercial invoice attested by AD I&E Peshawar, DRAP dated 18-01-2019 for 410gm of Empagliflozin. **Metformin:** Firm has submitted cpy of commercial invoice attested by AD I&E Peshawar, DRAP dated 09-07-2021 for 100Kg of Metformin HCl.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.

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

Remarks of Evaluator:

Section #	Observations	Firm's response
3.2.S.1.3	Justify the declaration of solubility of Empagliflozin as "Practically insoluble in water" with reference to the innovator drug product literature	Firm has submitted revised section of DMF.

Decision: Registration Board approved the applications of Empazin M 12.5/500 mg Tablet, Empazin M 5/850 mg Tablet & Empazin M 5/500 mg Tablet.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

54.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad, Pakistan**
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 17-12-2020 based on inspection conducted on 09-11-2020. Firm has submitted application for renewal of GMP certificate dated 10-11-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 15-12-2014 specifying Tablet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 12632 dated 24-05-2022
	Details of fee submitted	Rs.75,000/- dated 12-05-2022
	The proposed proprietary name / brand name	**Empala 25/5 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet contains: Empagliflozin ……... 25mg Linagliptin ……..…… 5mg
	Pharmacotherapeutic Group of (API)	**Empagliflozin:** Anti-Diabetic **Linagliptin:** Anti-Diabetic
	Pharmaceutical form of applied drug	Pink color hexagonal shape film coated tablets
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	7's, 10's, 14's, 20's, 28's & 30's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Glyxambi Tablets 10mg/5mg (FDA Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Empagliflozin:** **Name:** Kaifeng Pharmaceutical (Group) Company Limited. **Address:** No.1, Yunan Street, Kaifeng, Henan Province, China. **Linagliptin:** **Name:** Glenmark Life Sciences Limited **Address:** Plot No 3109, GIDC Industrial Estate, Ankleshwar District Bharuch, Gujarat - 393 002, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance of both API's separately and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance of both API's separately.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 06 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. **Linagliptin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 06 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Glyxambi Tablets by Boehringer Ingelheim Pharmaceuticals. Firm has submitted CDP results of their product against the

		innovator's product Glyxambi Tablets 10mg/5mg in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Empagliflozin:** **Name:** Kaifeng Pharmaceutical (Group) Company Limited. **Address:** No.1, Yunan Street, Kaifeng, Henan Province, China. **Linagliptin:** **Name:** Glenmark Life Sciences Limited **Address:** Plot No 3109, GIDC Industrial Estate, Ankleshwar District Bharuch, Gujarat - 393 002, India		
API Lot No.	**Empagliflozin:** HF190115 **Linagliptin:** 801900693		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01-2020	01-2020	01-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Previous approval of applications with stability study data of our product Tanavul Tablets 10mg which was approved in 320th meeting of Registration Board. The report confirms following points: iii. The HPLC software is 21CFR compliant. iv. Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of GMP Certificate (No. HA20190069) dated 29-09-2019 issued by China Food and Drug Administration. **Linagliptin:** Firm has submitted copy of GMP Certificate (No. 19061427) dated 18-06-2019 issued by Food and Drugs Control Administration Gujrat State India. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice cleared on 31-01-2019 specifying 5Kgs of Empagliflozin. The invoice is cleared by AD (I&E) DRAP, Islamabad. **Linagliptin:**

		Firm has submitted copy of commercial invoice cleared on 23-04-2019 specifying 0.038Kg of Linagliptin. The invoice is cleared by AD (I&E) DRAP, Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

55.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bosch Pharmaceuticals (Pvt.) Ltd. Plot no. 209, Sector 23, Korangi Industrial area, Karachi**
	Name, address of Manufacturing site.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Plot no. 209, Sector 23, Korangi Industrial area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate based on inspection conducted on 26-06-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Renewal of DML issued by Secretary CLB dated 21-06-2021 specifying Sterile Infusion (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 5851 dated 03-03-2022 Rs.30,000/- dated 10-11-2021
	The proposed proprietary name / brand name	**Boschstat 12.5mg/50ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Tirofiban HCl Eq. to Tirofiban…0.25mg
	Pharmacotherapeutic Group of (API)	Anti thrombic agent
	Pharmaceutical form of applied drug	Injection
	Reference to Finished product	Innovator's Specifications

	specifications	
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Aggrastat Injection 12.5mg/50ml approved by TGA of Asutralia
	For generic drugs (me-too status)	Aggrastat injection of M/s Atco Laboratories (Reg.#025299)
	Name and address of API manufacturer.	M/s Xi'an Wanlong Pharmaceutical Co., Ltd. no. 5 Chuangxin road, New Industrial park, gaoxin District, Xi'an Shaanxi, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance of both API's separately.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 6 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Aggrastat injection of M/s Siegfried
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Xi'an Wanlong Pharmaceutical Co., Ltd. no. 5 Chuangxin road, New Industrial park, gaoxin District, Xi'an Shaanxi, China
API Lot No.	YD-20201101-H
Description of Pack (Container closure system)	Glass vial
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-BOINJ-02	TR-BOINJ-03	TR-BOINJ-04
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	05-2021	05-2021	05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to previously approved product of Boschofen 400mg/100ml on basis of PSI, presented in 296th meeting of Registration Board. The report confirms following points: v. The HPLC software is 21CFR compliant. vi. Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. SN20190380) valid till 02-09-2024 issued by CFDA.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice no. 20201221 specifying 50g of Tirofiban HCl. The invoice is cleared by AD (I&E) DRAP,Karachi dated 11-01-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section #	Observations	Firm's response
1.3	• Latest GMP inspection report of the drug product manufacturer shall be submitted, conducted within last three years. • Evidence of availability of required manufacturing facility for filling of 50ml vial shall be submitted.	Firm has submitted copy of panel inspection report dated 10-04-2023 concluding Good cGMP compliance.
3.2.S.4.4	As per submitted analytical record, the chromatographic condition of wavelength declared on chromatograms of Assay test is different form that specified in drug substance analytical procedure. Justification shall be submitted in this regard	We Performed analysis of drug substance as Specified in drug substance analytical procedure kindly find attached assay results performed on same wave length (227 nm) as related substance analysis also performed on same wave length and we performed analytical method validation on same wave length as well as per submitted analytical procedure AMV chart enclosed for ready reference)

		we have enclosed assay analysis record of drug substance for your perusal as previously submitted assay analysis (274 nm) on 16-01-2021 due to analyst misunderstanding then we performed again assay on 227nm wave length as specified in drug substance analytical procedure on 19-01-2021 we regret for not submitted assay results at the time of submission.
3.2.P.5.1	Justification shall be submitted for limits of filled volume.	Boschstat injection standard filled volume = 51ml is kept as per following reference: Reference: USP, General Chapter (1151) Pharmaceutical Dosage Forms "EXCESS VOLUME IN INJECTIONS" Each container of an injection is filled with a volume in slight excess of the labeled "size" or the volume that is to be withdrawn. The excess volumes recommended in the said chapter allows fill volume upto 51ml, whereas firm has specified limit of 50-53ml.
3.2.P.5.5	Justification shall be submitted for the limits of impurities specified in drug product specifications.	Limit of impurities specified in drug product specification is taken (unspecified impurity NMT 0.1%) these limits are in compliance as per ICH guideline Q3B(R2).
3.2.P.8.3	• Date of analysis mentioned on stability summary sheets is prior to the date of manufacturing of stability batches. • Stability study data of 6th month time point shall be submitted.	Firm has submitted revised stability summary sheets with wherein date of analysis has been revised. Submitted 6th month data.
--	Justification shall be submitted for the dispensed quantity of Tirofiban HCl for each trial batch considering the potency of drug substance determined and theoretical factor for Tirofiban base.	Calculation submitted on basis of theoretical factor and potency on as is basis.

Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

56.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd., 16, K.O.C.H.S. Amir Khusro Road, Karachi-75350, Pakistan**
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	GMP status of the Finished product manufacturer	Renewal of license granted on 01/06/2021

		Tablet, Capsule, Ointment/Cream, Sachet, Dry Powder Inhalaer & Dry Powder suspension (General) sections approved. Last inspection conducted on 16-11-2021 and concludes that firm was considered to be operating at Good level of compliance
	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)
	Dy. No. and date of submission	Dy.No 4783 dated 14-02-2022
	Details of fee submitted	Rs.30,000/- dated 20-05-2022
	The proposed proprietary name / brand name	**Sciampa-M XR 12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin (as Immidiate Release Coating) ……. 12.5mg Metformin HCl (as Extended Release Core) …….1000mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-hyperglycemic agents (A10BD20)
	Reference to Finished product specifications	Manufacturer's
	Proposed Pack size	14's & 28's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	**Synjardy XR** 12.5mg/1gm extended release tablet by Boehringer Ingelheim (**U.S. FDA** Approved).
	For generic drugs (me-too status)	**XENGLU-MET XR** of M/s HILTON PHARMA (PVT.) LTD
	Name and address of API manufacturer.	**API manufacturer of Empagliflozin** Name: Fuxin Long Rui Pharmaceutical CO., Ltd. Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **API manufacturer of Metformin Hydrochloride** Name: Shouguang Fukang Pharmaceutical Co., Ltd. Address: North-East of Dongwaihuan Road, Dongcheng Industrial Area
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data for

		both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of both API at accelerated as well as real time conditions. The real time stability data of Empagliflozin conducted at 30±2°C, 65%±5% RH. The stability study data is till 26 months. The real time stability data of Metformin hydrochloride conducted at 30±2°C, 75%±5% RH. The stability study data is till 60 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Compartitive dissolution profile against Xenglu Met XR 5+1000mg Tablet of Hilton Pharma.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.

STABILITY STUDY DATA

API Lot No.	A-35212009047 / H-E-20201125-D03-E06-02		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	046B21	047B21	048B21
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	03-2021	03-2021	03-2021
No. of Batches	03		

57.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd., 16, K.O.C.H.S. Amir Khusro Road, Karachi-75350, Pakistan**
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi

	GMP status of the Finished product manufacturer	Renewal of license granted on 01/06/2021 Tablet, Capsule, Ointment/Cream, Sachet, Dry Powder Inhalaer & Dry Powder suspension (General) sections approved. Last inspection conducted on 16-11-2021 and concludes that firm was considered to be operating at Good level of compliance
	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)
	Dy. No. and date of submission	Dy.No 4175 dated 14-02-2022
	Details of fee submitted	Rs.30,000/- dated 20-05-2022
	The proposed proprietary name / brand name	**Sciampa-M XR 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin (as Immidiate Release Coating) ……. 5mg Metformin HCl (as Extended Release Core) …….1000mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-hyperglycemic agents (A10BD20)
	Reference to Finished product specifications	Manufacturer's
	Proposed Pack size	14's & 28's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	**Synjardy XR** 5mg/1gm extended release tablet by Boehringer Ingelheim (**U.S. FDA** Approved).
	For generic drugs (me-too status)	**XENGLU-MET XR** of M/s HILTON PHARMA (PVT.) LTD (Reg #105268)
	Name and address of API manufacturer.	**API manufacturer of Empagliflozin** Name: Fuxin Long Rui Pharmaceutical CO., Ltd. Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **API manufacturer of Metformin Hydrochloride** Name: Shouguang Fukang Pharmaceutical Co., Ltd. Address: North-East of Dongwaihuan Road, Dongcheng Industrial Area
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of both API at accelerated as well as real time conditions. The real time stability data of Empagliflozin conducted at 30±2°C, 65%±5% RH. The stability study data is till 26 months. The real time stability data of Metformin hydrochloride conducted at 30±2°C, 75%±5% RH. The stability study data is till 60 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Compartitive dissolution profile against Xenglu Met XR 5+1000mg Tablet of Hilton Pharma.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.

STABILITY STUDY DATA			
API Lot No.	A-35212009047 / H-E-20201125-D03-E06-02		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	049B21	050B21	051B21
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	03-2021	03-2021	03-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Glusimet XR 50/500mg Tablets & Glusimet XR 50/1000mg Tablets which was conducted on 16th

		July, 2020 and was presented in 296th meeting of Registration Board held on 8th - 10th September, 2020. According to the report following points were confirmed. □ The firm has 21 CFR compliant HPLC software □ The firm has audit trail reports available. □ The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin** Copy of DML certificate No. Liao20150233 issued by FDA of Liaoning Province valid till 20/12/2022 & GMP Certificate No. LN210014 valid till 25-05-2024. **Metformin HCl:** Copy of GMP certificate No. SD20190888 issued by CFDA valid till 12/03/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of form 5, invoice (invoice# HN201110-J) cleared by DRAP Karachi office dated 09-02-2021 specifying import 10Kg Empagliflozin (Batch# H-E-20201125-D03-E06-02). **Metformin HCl:** Firm has submitted copy of invoice from Shouguang Fukang Pharmaceutical Co., Ltd. cleared by DRAP Karachi office dated 19-01-2021 specifying import 2000Kg Metformin HCl (Batch# A-35212009047
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Section#	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate of M/s Fuxin Long Rui, issued by relevant authority of country of origin.	
	Empagliflozin	
3.2.S.1.3	• In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	
3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
3.2.S.5	• Submitted COA of working standard declares expire date as 18-04-2018, whereas drug	

	substance analysis has been performed subsequent to this date.	
	Metformin HCl	
3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted. • standard declares expire date as 18-04-2018, whereas drug substance analysis has been performed subsequent to this date.	
3.2.S.5	• Submitted COA of working used by M.s Scilife for performance of drug substance analysis.	
3.2.S.7.3	• Long term stability studies as per Zone IV conditions shall be submitted.	
3.2.P.1	• Justification shall be submitted on basis of performance based evidence for adding overage of "Empagliflozin" in the applied batch formulation.	
3.2.P.8.3	• Justification shall be submitted for the ascending trend of Assay results in stability studies. • Justification shall be submitted for the in-process tests adopted for the confirmation of dissolution profile of Metformin HCl core and assay content of Empagliflozin. • Minimum handling capacities of the equipments used in the production of stability trial batches, shall be submitted. • Justification shall be submitted for the significant changes in Assay results of Empagliflozin reported in accelerated stability studies. • Reconciliation record for the imported quantity of Empagliflozin shall be submitted.	

Decision: Registration Board deferred the applications of Sciampa-M XR 12.5/1000 mg Tablet & Sciampa-M XR 5/1000 mg Tablet for submission of reply to the above cited shortcomings

Case no. 03 Registration applications for local manufacturing of (Human) drugs of New DML/New Section.

- CLB in its 290th meeting held on 28-04-2023 has approved grant of additional sections including Dry Powder Injection (Cephalosporin), in name of M/s Crystolite Pharmaceuticals Plot # 1,2 street s-2 national industrial zone Rawat Islamabad.

58.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Crystolite Pharmaceuticals Plot # 1,2 street s-2 national industrial zone Rawat Islamabad.**
	Name, address of Manufacturing site.	M/s Crystolite Pharmaceuticals Plot # 1,2 street s-2 national industrial zone Rawat Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: SP2-GW7-LLZN dated 09-02-2024
	Details of fee submitted	Rs.30,000/- dated 11-01-2024
	The proposed proprietary name / brand name	**Osotax 2gm injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone as sodium……..2g
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP

EVALUATION OF DATA

GMP status of the firm	cGMP certificate issued on basis of inspection conducted on 08-08-2022
Evidence of approval of manufacturing facility	Firm has submitted letter of issuance of additional section declaring grant of Dry Powder Injection (Cephalosporin) section.
Proposed Pack size	1's
Proposed unit price	As per SRO
The status in reference regulatory authorities	MHRA approved
For generic drugs (me-too status)	Oxidil 2g IV Injection by SAMI Pharmaceuticals.
Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has performed pharmaceutical equivalence against the product Oxidil 2g IV Injection by Sami Pharmaceuticals
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	Q012212069		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30°C ±2°C / 65%±5% RH Accelerated: 40°C ±2°C / 75%±5% RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	028T23	029T23	030T23
Batch Size	333 Vials	333 Vials	333 Vials
Manufacturing Date	08-2023	08-2023	08-2023

No. of Batches	03

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No.SX20180229) dated 06-06-2018 issued by Shangxi province Food and Drug Administration, China.
Documents for the procurement of API with approval from DRAP (in case of import).	➢ Firm has submitted loan letter from M/s Pearl Pharmaceuticals. ➢ Firm has submitted Clearance certificate issued dated 20-01-2023 for import of 100Kg of Ceftriaxone sodium issued in name of M/s Pearl Pharmaceuticals.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product stability studies.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC^{II}:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.P.8.3**	• Submit 6th month time point stability data for both accelerated and long term stability studies.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

CLB in its 290th meeting held on 28-04-2023 has approved grant of DML#000971 including "Dry Powder Injection (Penicillin) section, in name of M/s Skywin Pharmaceuticals Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore, Pakistan.

59.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Skywin Pharmaceuticals Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore, Pakistan.**
	Name, address of Manufacturing site.	M/s Skywin Pharmaceuticals Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: WAY-1L2-D2JG dated 13-03-2024
	Details of fee submitted	Rs.30,000/- dated 20-12-2023
	The proposed proprietary name / brand name	**Tazopip Injection 2.25 g**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Piperacillin (as Piperacillin Sodium) ……2.0 g Tazobactam (as Tazobactam Sodium) ……. 0.25 g
	Pharmacotherapeutic Group of (API)	β-Lactamase inhibitor
	Reference to Finished product specifications	USP

EVALUATION OF DATA	
GMP status of the firm	cGMP certificate issued on basis of inspection conducted on 08-08-2022
Evidence of approval of manufacturing facility	grant of DML#000971 including "Dry Powder Injection (Penicillin) section
Proposed Pack size	1's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Zosyn ® Injection is Approved in USFDA
For generic drugs (me-too status)	Tanzo Injection 2.25gm by Bosch Pharmaceuticals.
Name and address of API manufacturer.	M/s Shandong Anxin Pharmaceutical Co., Ltd, No.849 Dongjia Town, Licheng District, Jinan, Shandong, 250105 China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has performed pharmaceutical equivalence against the product Tanzo Injetion 4.5gm Injection by M/s Bosch Pharmaceuticals
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
API Lot No.	HF2164D3

Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30°C ±2°C / 65%±5% RH Accelerated: 40°C ±2°C / 75%±5% RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T1	T2	--
Batch Size	2000 vials	2000 vials	--
Manufacturing Date	04-2023	04-2023	--
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML Certificate (No.2016009) valid upto 20160009
Documents for the procurement of API with approval from DRAP (in case of import).	➢ Firm has submitted loan letter from M/s Stallion Pharmaceuticals. ➢ Firm has submitted Clearance certificate issued dated 12-01-2023 for import of Pipracillin/Tazobactam issued in name of M/s Stallion Pharmaceuticals.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product stability studies.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[II]:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

60.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Skywin Pharmaceuticals Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore, Pakistan.**
	Name, address of Manufacturing site.	M/s Skywin Pharmaceuticals Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: SX9-YH7-35P7 dated 13-03-2024
	Details of fee submitted	Rs.30,000/- dated 20-12-2023
	The proposed proprietary name / brand name	**Tazopip Injection 4.5 g**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Piperacillin (as Piperacillin Sodium) ……4.0 g Tazobactam (as Tazobactam Sodium) ……. 0.5 g
	Pharmacotherapeutic Group of (API)	β-Lactamase inhibitor
	Reference to Finished product specifications	USP

EVALUATION OF DATA	
GMP status of the firm	cGMP certificate issued on basis of inspection conducted on 08-08-2022
Evidence of approval of manufacturing facility	grant of DML#000971 including "Dry Powder Injection (Penicillin) section
Proposed Pack size	1's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Zosyn ® Injection is Approved in USFDA
For generic drugs (me-too status)	Tanzo Injection 4.5gm by Bosch Pharmaceuticals.
Name and address of API manufacturer.	M/s Shandong Anxin Pharmaceutical Co., Ltd, No.849 Dongjia Town, Licheng District, Jinan, Shandong, 250105 China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has performed pharmaceutical equivalence against the product Tanzo Injetion 4.5gm Injection by M/s Bosch Pharmaceuticals
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	HF2164D3		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30°C ±2°C / 65%±5% RH Accelerated: 40°C ±2°C / 75%±5% RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T1	T2	--
Batch Size	2000 vials	2000 vials	--
Manufacturing Date	04-2023	04-2023	--
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML Certificate (No.2016009) valid upto 20160009
Documents for the procurement of API with approval from DRAP (in case of import).	➢ Firm has submitted loan letter from M/s Stallion Pharmaceuticals. ➢ Firm has submitted Clearance certificate issued dated 12-01-2023 for import of Pipracillin/Tazobactam issued in name of M/s Stallion Pharmaceuticals.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product stability studies.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC^{II}:	
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	

➢ CLB in its 292nd meeting held on 04-10-2023 has approved grant of additional sections of Syrup Section General, in name of M/s Genetics Pharmaceuticals (Pvt.) Ltd. Address: 539-A, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan

61.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt.) Ltd. Address: 539-A, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan**
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals (Pvt.) Ltd. Address: 539-A, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 6NW-E4X-5BEM dated 11-03-2024
	Details of fee submitted	Rs.75,000/- dated 16-01-2024
	The proposed proprietary name / brand name	**Paroxogen Oral Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Paroxetine Hydrochloride equivalent to Paroxetine…..10mg
	Pharmacotherapeutic Group of (API)	Selective Serotonin Reuptake Inhibitor / Anti-Depressants

	Reference to Finished product specifications	As per Innovator specifications

EVALUATION OF DATA	
GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-03-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 25-10-2023 specifying Syrup section.
Proposed Pack size	1's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Paxil 10mg base/5mL Oral Suspension (USFDA Approved)
For generic drugs (me-too status)	NA
Name and address of API manufacturer.	M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Address: Xunqiao, Linhai, Zhejiang 317024, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Paxil 10mg/5mL Oral Suspension manufactured by GSK.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	5669-21-032		
Description of Pack (Container closure system)	Plastic bottle		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	GN-001	GN-002	--
Batch Size	2000	2000	--
Manufacturing Date	04-2022	04-2022	--
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML (20000311) of M/s Zhejiang Huahai Pharmaceutical Co., Ltd. China
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice HH20212406 cleared on 06-11-2021 specifying 53kg of Paroxetine HCL Hemihydrate. The invoice is cleared by AD (I&E) DRAP, Lahore

Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product stability studies.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC[II]:	
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	

- CLB in its 289th meeting held on 22-02-2023 has approved grant of additional sections including Tablet (penicillin) Section, in name of M/s Stallion Pharmaceuticals, PVT, LTD. Plot No. 581, Sundar Industrial Estate, Raiwind Road, Lahore

62.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Stallion Pharmaceuticals, PVT, LTD. Plot No. 581, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals, PVT, LTD. Plot No. 581, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: D1B-8U1-J2ZU dated 22-03-2024
	Details of fee submitted	Rs.30,000/- dated 08-09-2023
	The proposed proprietary name / brand name	**Stamentin 625mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Amoxicillin as Trihydrate …….500mg Clavulanic acid as Potassium Clavulanate …. 125 mg
	Pharmacotherapeutic Group of (API)	Antibacterial for systematic use, carbapenem.
	Reference to Finished product specifications	USP
EVALUATION OF DATA		
GMP status of the firm		cGMP certificate issued on basis of inspection conducted on 20-09-2022
Evidence of approval of manufacturing facility		Firm has submitted letter of issuance of additional section declaring grant of Penicillin (Tablet) section.
Proposed Pack size		6's
Proposed unit price		As per SRO
The status in reference regulatory authorities		Approved by US FDA
For generic drugs (me-too status)		Calamox 625 mg Table of M/s Bosch Pharma (Reg.#021510)

Name and address of API manufacturer.	**Amoxicillin trihydrate:** M/s. Saakh Pharma Pvt. Ltd. Plot # C-7/1, North West Industrial Zone, Port Qasim, Karachi, Pakistan **Potassium Clavulanate:** M/s Zhuhai United Labs (CHINA) No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong Province, 519040 P.R. China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Augmentin 625mg Tablet. Firm has submitted CDP results of their product against the innovator's product Augmentin 625mg Tablet.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	Potassium Clavulanate: 3572301434 Amoxicillin trihydrate: 23PN3-20023		
Description of Pack (Container closure system)	Aluminium foil		
Stability Storage Condition	Real time: 30°C ±2°C / 65%±5% RH Accelerated: 40°C ±2°C / 75%±5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST2-01	ST2-02	ST2-03
Batch Size	1834 tablets	1834 tablets	1834 tablets
Manufacturing Date	05-2023	05-2023	05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Amoxicillin trihydrate:** GMP certificate issued by Additional Director I&E, DRAP Karachi issued on basis of inspection conducted on 7-10-2022. **Potassium Clavulanate:** Firm has submitted GMP certificate no. GD20180909 issued by CFDA valid till 05-12-2023.
Documents for the procurement of API with approval from DRAP (in case of import).	➢ Firm has submitted commercial invoice from M/s Saakh pharma. ➢ Firm has submitted Clearance certificate issued dated 03-05-2023 for import of 100Kg of Clavulanate potassium.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

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

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.P.8.3**	Submit stability studies data of 6th month time point.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

63.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Stallion Pharmaceuticals, PVT, LTD. Plot No. 581, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals, PVT, LTD. Plot No. 581, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: RDB-6H8-83E4 dated 22-03-2024
	Details of fee submitted	Rs.30,000/- dated 08-09-2023
	The proposed proprietary name / brand name	**Stamentin 375mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Amoxicillin as Trihydrate …….250mg Clavulanic acid as Potassium Clavulanate …. 125 mg
	Pharmacotherapeutic Group of (API)	Antibacterial for systematic use, carbapenem.
	Reference to Finished product specifications	USP

EVALUATION OF DATA

GMP status of the firm	cGMP certificate issued on basis of inspection conducted on 20-09-2022
Evidence of approval of manufacturing facility	Firm has submitted letter of issuance of additional section declaring grant of Penicillin (Tablet) section.
Proposed Pack size	6's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Calamox 625 mg Table of M/s Bosch Pharma (Reg.#021510)
Name and address of API manufacturer.	**Amoxicillin trihydrate:** M/s. Saakh Pharma Pvt. Ltd. Plot # C-7/1, North West Industrial Zone, Port Qasim, Karachi, Pakistan **Potassium Clavulanate:** M/s Zhuhai United Labs (CHINA) No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong Province, 519040 P.R. China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.

Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Augmentin 375mg Tablet. Firm has submitted CDP results of their product against the innovator's product Augmentin 625mg Tablet.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

API Lot No.	Potassium Clavulanate: 3572301434 Amoxicillin trihydrate: 23PN3-20023		
Description of Pack (Container closure system)	Aluminium foil		
Stability Storage Condition	Real time: 30°C ±2°C / 65%±5% RH Accelerated: 40°C ±2°C / 75%±5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST1-01	ST1-02	ST1-03
Batch Size	2836 tablets	2836 tablets	2836 tablets
Manufacturing Date	05-2023	05-2023	05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Amoxicillin trihydrate:** GMP certificate issued by Additional Director I&E, DRAP Karachi issued on basis of inspection conducted on 7-10-2022. **Potassium Clavulanate:** Firm has submitted GMP certificate no. GD20180909 issued by CFDA valid till 05-12-2023.
Documents for the procurement of API with approval from DRAP (in case of import).	➢ Firm has submitted commercial invoice from M/s Saakh pharma. ➢ Firm has submitted Clearance certificate issued dated 03-05-2023 for import of 100Kg of Clavulanate potassium.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response

1.	**3.2.P.8.3**	Submit stability studies data of 6th month time point.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

64.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Stallion Pharmaceuticals, PVT, LTD. Plot No. 581, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals, PVT, LTD. Plot No. 581, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: SM8-RQZ-RRGJ dated 22-03-2024
	Details of fee submitted	Rs.30,000/- dated 08-09-2023
	The proposed proprietary name / brand name	**Stamentin 1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Amoxicillin as Trihydrate …….875mg Clavulanic acid as Potassium Clavulanate …. 125 mg
	Pharmacotherapeutic Group of (API)	Antibacterial for systematic use, carbapenem.
	Reference to Finished product specifications	USP

EVALUATION OF DATA

GMP status of the firm	cGMP certificate issued on basis of inspection conducted on 20-09-2022
Evidence of approval of manufacturing facility	Firm has submitted letter of issuance of additional section declaring grant of Penicillin (Tablet) section.
Proposed Pack size	6's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Calamox 625 mg Table of M/s Bosch Pharma (Reg.#021510)
Name and address of API manufacturer.	**Amoxicillin trihydrate:** M/s. Saakh Pharma Pvt. Ltd. Plot # C-7/1, North West Industrial Zone, Port Qasim, Karachi, Pakistan **Potassium Clavulanate:** M/s Zhuhai United Labs (CHINA) No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong Province, 519040 P.R. China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Augmentin 375mg Tablet.

	Firm has submitted CDP results of their product against the innovator's product Augmentin 625mg Tablet.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	Potassium Clavulanate: 3572301434 Amoxicillin trihydrate: 23PN3-20023		
Description of Pack (Container closure system)	Aluminium foil		
Stability Storage Condition	Real time: 30°C ±2°C / 65%±5% RH Accelerated: 40°C ±2°C / 75%±5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST3-01	ST3-02	ST3-03
Batch Size	1305 tablets	1305 tablets	1305 tablets
Manufacturing Date	05-2023	05-2023	05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Amoxicillin trihydrate:** GMP certificate issued by Additional Director I&E, DRAP Karachi issued on basis of inspection conducted on 7-10-2022. **Potassium Clavulanate:** Firm has submitted GMP certificate no. GD20180909 issued by CFDA valid till 05-12-2023.
Documents for the procurement of API with approval from DRAP (in case of import).	➢ Firm has submitted commercial invoice from M/s Saakh pharma. ➢ Firm has submitted Clearance certificate issued dated 03-05-2023 for import of 100Kg of Clavulanate potassium.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.P.8.3**	Submit stability studies data of 6th month time point.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

- CLB in its 292nd meeting held on 04-10-2023 has approved grant of additional sections including Suppository Section, in name of M/s Genix pharma (Pvt.) Ltd. 44, 45B, Korangi creek road, Karachi

65.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 9UT-P6P-P161 dated 19-1-2024
	Details of fee submitted	Rs.75,000/- dated 05-01-2024
	The proposed proprietary name / brand name	**KARMOL Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains: Paracetamol …… 500mg
	Pharmacotherapeutic Group of (API)	Analgesic (ATC code: N02AX02)
	Reference to Finished product specifications	USP

EVALUATION OF DATA	
GMP status of the firm	cGMP certificate issued on basis of inspection conducted on 06-06-2023
Evidence of approval of manufacturing facility	Firm has submitted letter of issuance of additional section declaring grant of Suppository section.
Proposed Pack size	1's, 5's, 10's, 20's.
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by HPRA of Ireland
For generic drugs (me-too status)	N/A
Name and address of API manufacturer.	M/s. Pharmagen Private Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product Tipol suppository of Clonmel Healthcare Ltd, Ireland.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
API Lot No.	00510911/269/2023
Description of Pack	Aluminium foil

(Container closure system)			
Stability Storage Condition	Real time: 5°C ± 3°C Accelerated: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	23SB-127-01	23SB-128-02	23SB-129-03
Batch Size	100 suppositories	100 suppositories	100 suppositories
Manufacturing Date	09-2023	09-2023	09-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate issued by DRAP Lahore, on basis of inspection conducted on 18-11-2022
Documents for the procurement of API with approval from DRAP (in case of import).	Locally purchased.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time stability studies and manual record for the accelerated stability chambers.

Evaluation by PEC^{II}:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.P.5.1**	Justification shall be submitted for not including following tests in drug product specifications, as recommended by USP General chapter <4 > & <1004>: • Uniformity of Dosage units • Softening time of lipophilic suppositories • Drug Release test	
2.	**3.2.P.2.2.1**	Justification shall be submitted for not performing comparative studies for drug release test against the innovator/reference product.	
3.	**3.2.P.8.3**	• Submit justification for performing stability studies at following conditions, instead of the recommended conditions of Zone IV for General products: Real time: 5°C ± 3°C Accelerated: 30°C ± 2°C / 65% ± 5%RH • Justification shall be submitted for the proposed batch size against the number of units required for the complete stability studies till claimed shelf life.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
66.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: AVG-ZWT-RGQ5 dated 21-02-2024
	Details of fee submitted	Rs.75,000/- dated 29-01-2024
	The proposed proprietary name / brand name	**KARMOL Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains: Paracetamol …… 1000mg
	Pharmacotherapeutic Group of (API)	Analgesic (ATC code: N02AX02)
	Reference to Finished product specifications	USP

EVALUATION OF DATA	
GMP status of the firm	cGMP certificate issued on basis of inspection conducted on 06-06-2023
Evidence of approval of manufacturing facility	Firm has submitted letter of issuance of additional section declaring grant of Suppository section.
Proposed Pack size	1's, 5's, 10's, 20's.
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by HPRA of Ireland
For generic drugs (me-too status)	N/A
Name and address of API manufacturer.	M/s. Pharmagen Private Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product Tipol suppository of Clonmel Healthcare Ltd, Ireland.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
API Lot No.	00510911/269/2023
Description of Pack (Container closure system)	Aluminium foil
Stability Storage Condition	Real time: 5°C ± 3°C Accelerated: 30°C ± 2°C / 65% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	23SB-498-01	23SB-499-02	23SB-500-03
Batch Size	100 suppositories	100 suppositories	100 suppositories
Manufacturing Date	09-2023	09-2023	09-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate issued by DRAP Lahore, on basis of inspection conducted on 18-11-2022
Documents for the procurement of API with approval from DRAP (in case of import).	Locally purchased.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time stability studies and manual record for the accelerated stability chambers.

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.P.5.1**	Justification shall be submitted for not including following tests in drug product specifications, as recommended by USP General chapter <4 > & <1004>: • Uniformity of Dosage units • Softening time of lipophilic suppositories • Drug Release test	
2.	**3.2.P.2.2.1**	Justification shall be submitted for not performing comparative studies for drug release test against the innovator/reference product.	
3.	**3.2.P.8.3**	• Submit justification for performing stability studies at following conditions, instead of the recommended conditions of Zone IV for General products: Real time: 5°C ± 3°C Accelerated: 30°C ± 2°C / 65% ± 5%RH • Justification shall be submitted for the proposed batch size against the number of units required for the complete stability studies till claimed shelf life.	

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

67.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**

	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: V5H-ZTH-U3Y1 dated 12-02-2024
	Details of fee submitted	Rs.30,000/- dated 05-01-2024
	The proposed proprietary name / brand name	**KARMOL Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains: Paracetamol …… 125mg
	Pharmacotherapeutic Group of (API)	Analgesic (ATC code: N02AX02)
	Reference to Finished product specifications	USP

EVALUATION OF DATA	
GMP status of the firm	cGMP certificate issued on basis of inspection conducted on 06-06-2023
Evidence of approval of manufacturing facility	Firm has submitted letter of issuance of additional section declaring grant of Suppository section.
Proposed Pack size	1's, 5's, 10's, 20's.
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by HPRA of Ireland
For generic drugs (me-too status)	N/A
Name and address of API manufacturer.	M/s. Pharmagen Private Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product Tipol suppository of Clonmel Healthcare Ltd, Ireland.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
API Lot No.	00510911/269/2023
Description of Pack (Container closure system)	Aluminium foil
Stability Storage Condition	Real time: 5°C ± 3°C Accelerated: 30°C ± 2°C / 65% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	23SB-080-01	23SB-081-02	23SB-082-03
Batch Size	100 suppositories	100 suppositories	100 suppositories
Manufacturing Date	09-2023	09-2023	09-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate issued by DRAP Lahore, on basis of inspection conducted on 18-11-2022
Documents for the procurement of API with approval from DRAP (in case of import).	Locally purchased.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time stability studies and manual record for the accelerated stability chambers.

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.P.5.1**	Justification shall be submitted for not including following tests in drug product specifications, as recommended by USP General chapter <4 > & <1004>: • Uniformity of Dosage units • Softening time of lipophilic suppositories • Drug Release test	
2.	**3.2.P.2.2.1**	Justification shall be submitted for not performing comparative studies for drug release test against the innovator/reference product.	
3.	**3.2.P.8.3**	• Submit justification for performing stability studies at following conditions, instead of the recommended conditions of Zone IV for General products: Real time: 5°C ± 3°C Accelerated: 30°C ± 2°C / 65% ± 5%RH • Justification shall be submitted for the proposed batch size against the number of units required for the complete stability studies till claimed shelf life.	

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

68.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Z6Z-99G-7G47 dated 19-01-2024
	Details of fee submitted	Rs.30,000/- dated 05-01-2024
	The proposed proprietary name / brand name	**KARMOL Suppository**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each suppository contains: Paracetamol …… 250mg
	Pharmacotherapeutic Group of (API)	Analgesic (ATC code: N02AX02)
	Reference to Finished product specifications	USP

EVALUATION OF DATA	
GMP status of the firm	cGMP certificate issued on basis of inspection conducted on 06-06-2023
Evidence of approval of manufacturing facility	Firm has submitted letter of issuance of additional section declaring grant of Suppository section.
Proposed Pack size	1's, 5's, 10's, 20's.
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by HPRA of Ireland
For generic drugs (me-too status)	N/A
Name and address of API manufacturer.	M/s. Pharmagen Private Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product Tipol suppository of Clonmel Healthcare Ltd, Ireland.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	00510911/269/2023		
Description of Pack (Container closure system)	Aluminium foil		
Stability Storage Condition	Real time: 5°C ± 3°C Accelerated: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	23SB-093-01	23SB-094-02	23SB-095-03
Batch Size	100 suppositories	100 suppositories	100 suppositories
Manufacturing Date	09-2023	09-2023	09-2023

No. of Batches	03
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate issued by DRAP Lahore, on basis of inspection conducted on 18-11-2022
Documents for the procurement of API with approval from DRAP (in case of import).	Locally purchased.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time stability studies and manual record for the accelerated stability chambers.

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.P.5.1**	Justification shall be submitted for not including following tests in drug product specifications, as recommended by USP General chapter <4 > & <1004>: • Uniformity of Dosage units • Softening time of lipophilic suppositories • Drug Release test	
2.	**3.2.P.2.2.1**	Justification shall be submitted for not performing comparative studies for drug release test against the innovator/reference product.	
3.	**3.2.P.8.3**	• Submit justification for performing stability studies at following conditions, instead of the recommended conditions of Zone IV for General products: Real time: 5°C ± 3°C Accelerated: 30°C ± 2°C / 65% ± 5%RH • Justification shall be submitted for the proposed batch size against the number of units required for the complete stability studies till claimed shelf life.	

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

- **M/s Carer Pharmaceuticals Industries,** Plot # 27, Main Road, Rawat Industrial Estate, Rawat. The Central Licensing Board in its 278th meeting held on 10th-11th December, 2020 has considered and approved the grant of Drug Manufacturing License by way of formulation with following five sections to M/s, Carer Pharmaceuticals Industries Plot # 27, Main Road, Rawat Industrial Estate, Rawat under Drug Manufacturing License No. 000925 by way of Formulation vide approval letter No. F. 1-32/2016-Lic dated 07th June 2021. The Drug Manufacturing License No. 000925 by way of formulation is hereby issued w.e.f. 18-03-2021.

1. Capsule Section (General) Section

2. Dry Powder Suspension (General) Section
3. Sachet (General) Section
4. Ampoule (General) Section
5. Tablet (General) Section

69.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.**
	Name, address of Manufacturing site.	M/s.Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 11465 dated 12-05-2022
	Details of fee submitted	Rs.30,000/- dated 20-04-2022
	The proposed proprietary name / brand name	**Carafin 50mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Diclofenac potassium enteric coated pellets eq to Diclofenac potassium ……. 50mg
	Pharmaceutical form of applied drug	White to off-white pellets filled in cap.shell.
	Pharmacotherapeutic Group of (API)	Analgesic
	Reference to Finished product specifications	Innovators specs.
	Proposed Pack size	As per
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	--
	For generic drugs (me-too status)	Catum mg Capsule by Fedro Pharmaceutical Peshawar
	GMP status of the Finished product manufacturer	New license granted on 07/06/2021 Tablet, capsule, dry powder and Ampule (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand r that is Catum 50mg Cap by Fedro pharmaceuticals performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Catum 50MG Capsule by Fedro P in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan		
API Lot No.	DE929ER		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3 , 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2500 cap	2500 cap	2500 cap
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	25-09-2021	25-09-2021	25-09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Datzend 20mg, Datzend 40mg, prezula 75mg,100mg capules etc.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F.3-26/2019 DRAP issued by DRAP valid till 09/05/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Local purchase from Vision Pharma Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr.#	Section#	Observation
1.	1.5.9	Submit evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since submitted reference is not approved in US FDA

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

70.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s.Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.**
	Name, address of Manufacturing site.	M/s.Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 11464 dated 12-05-2022
	Details of fee submitted	Rs.30,000/- dated 09-05-2022
	The proposed proprietary name / brand name	**Carafinac 100mg SR Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Diclofenac Sodium (as modified release Pellets)…...100mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Diclofenac sodium 100mg Modified Release capsule Approved by HPRA of Ireland
	For generic drugs (me-too status)	Product: Mobikare SR100mg capsules Manufacturer: M/S Barrett Hodgson Pakistan (Pvt) Ltd (Reg No 029393)
	GMP status of the Finished product manufacturer	New license granted on 07/06/2021 Tablet, capsule, dry powder and Ampule (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence & CDP studies have been submitted against Voren 100mg SR capsules.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA	
Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan
API Lot No.	DE929ER
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0,3 , 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2500 cap	2500 cap	2500 cap
Manufacturing Date	10-2021	10-2021	10-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F.3-26/2019 DRAP issued by DRAP valid till 09/05/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Local purchase from Vision Pharma Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

- CLB in its 292nd meeting held on 04-10-2023 has approved grant of additional sections including Dry Powder Inhalataion Secation, in name of M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan

71.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: G5A-DQL-V1NJ dated 27-03-2024
	Details of fee submitted	Rs.75,000/- dated 19-03-2024
	The proposed proprietary name / brand name	**Tresium 100mcg & 62.5mcg+25mcg DPI Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**For Capsule 1:** Each capsule contains: Fluticasone furoate…….…...100 mcg **For Capsule 2:** Each capsule contains: Umeclidinium (as bromide) …….62.5 mcg Vilanterol (as trifenatate) ……25 mcg **Each delivered dose contains:** Fluticasone furoate…….…...92 mcg Umeclidinium (as bromide) …….55 mcg Vilanterol (as trifenatate) ……22 mcg
	Pharmaceutical form of applied drug	DPI (Dry Powder Inhaler) Capsule
	Pharmacotherapeutic Group of (API)	Fluticasone furoate is an inhaled corticosteroid that can be used as maintenance treatment of asthma and/or chronic obstructive pulmonary disease (COPD) depending on the product. Umeclidinium is a long-acting muscarinic antagonist and Vilanterol is a selective long-acting β2-agonist.
	Reference to Finished product specifications	As per Innovator's Specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	"TRELEGY ELLIPTA" (fluticasone furoate, umeclidinium, and vilanterol inhalation powder) for oral inhalation use" (US-FDA Approved)

	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	Last inspection report dated 16.08.2022 concluded good level of cGMP compliance.
	Name and address of API manufacturer.	**Fluticasone Furoate:** VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA). **Umeclidinium Bromide:** Inke, S.A. Area Industrial del Llobregat C/Argent, 1 08755 Castellbisbal, Barcelona- Spain. **Vilanterol Trifenatate:** Inke, S.A. Area Industrial del Llobregat C/Argent, 1 08755 Castellbisbal, Barcelona- Spain.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Reference product that is Trelegy Ellipta Inhalation Powder by performing quality tests (Identification, Water contents, Foreign Particulate Matter, Assay, Delivered dose uniformity, Aerodynamic particle size distribution and Microbial Test.
	Analytical method validation/verification of product	Analytical method verification studies of both drug substances and Analytical Method Validation Studies have been submitted including Introduction, Verification/Validation of Assay method, Specificity, Accuracy, Precision, Linearity concentration and peak range.

STABILITY STUDY DATA		
Manufacturer of API	**Fluticasone Furoate:** VAMSI LABS LTD. **Umeclidinium Bromide:** Inke, S.A. **Vilanterol Trifenatate:** Inke, S.A.	
API Lot No.	**Fluticasone Furoate:** FTF (P)-0010121 **Umeclidinium Bromide:** PP-15M **Vilanterol Trifenatate:** P-12M	
Description of Pack (Container closure system)	60's Capsules packed in unit carton along with leaflet.	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 8, 12, 16, 18, 24 (Months)	
Batch No.	FVL-001	FVL-002
Batch Size	Capsule 1: 5000 Capsules Capsule 2: 5000 Capsules	Capsule 1: 5000 Capsules Capsule 2: 5000 Capsules

<table>
<tr><td colspan="2">Manufacturing Date</td><td>08– 2023</td><td>08– 2023</td></tr>
<tr><td colspan="2">Date of Initiation</td><td>15-08-2023</td><td>15-08-2023</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="2">02</td></tr>
<tr><td colspan="4">Administrative Portion</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="2">Firm has referred to onsite inspection report of this product:

XETINE 10mg Tablet, (Vortioxetine as Hydrobromide)

which was conducted on dated 06-07-2020 and was presented in 313th meeting of Registration Board held on 16-18 Nov, 2021.
Registration Board decided to approve registration of
XETINE 10mg Tablet, (Vortioxetine as Hydrobromide)
by M/s. Horizon Healthcare (Pvt) Ltd. Plot No. 35-A,
Small industrial Estate, Taxila, Pakistan. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
Following observations were reported in the report:
i. The HPLC software is 21 CFR compliant.
ii. Audit trail on the testing reports of XETINE 10mg Tablet, is available.
iii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.</td></tr>
<tr><td>2.</td><td>Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="2">Firm had provided valid GMP & Certificate of VAMSI LABS LTD. issued by FDA Maharashtra Valid upto: 04-10-2024

Firm had provided valid GMP & Certificate of Inke, S.A. issued by Govt. of Catalonia Valid upto: 27-07-2026</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="2">Copy of Clearance Certificate approved by DRAP attested by AD I&E, has been submitted.
Fluticasone Furoate:
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>FTF (P)-0010121</td><td>EXP/05/21-22</td><td>50 grams</td><td>30-Sep-2021</td></tr>
</table>
Umeclidinium Bromide:
<table>
<tr><th>Batch No.</th><th>Computerized No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>PP-15M</td><td>HORIZON02122021</td><td>50 grams</td><td>17-Sep-2021</td></tr>
</table>
Vilanterol Trifenatate:
<table>
<tr><th>Batch No.</th><th>Computerized No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>P-12M</td><td>HORIZON02122021</td><td>50 grams</td><td>17-Sep-2021</td></tr>
</table></td></tr>
</table>

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets have been submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.
Remarks of Evaluator [II]: Reference product "TRELEGY ELLIPTA" is available as beige plastic inhaler containing 2 foil blister strips. Each blister on one strip contains a white powder blend of micronized fluticasone furoate and each blister on the other strip contains a white powder blend of micronized umeclidinium bromide (74.2 mcg equivalent to 62.5 mcg of umeclidinium), micronized Vilanterol trifenatate (40 mcg equivalent to 25 mcg of vilanterol), magnesium stearate (75 mcg), and lactose monohydrate (12.3 mg). While the firm has replicated this presentation in two separate capsules presented in combo pack and accompanied by a delivery device wherein contents of both capsules can be administered simultaneously.		
Decision: Registration Board deferred the application for clarification of dose delivery mechanism against the innovator product along with details of delivery device to be accompanied with the applied product.		
72.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: XGD-PV1-97QY dated 27-03-2024
	Details of fee submitted	Rs.75,000/- dated 19-03-2024
	The proposed proprietary name / brand name	**Tresium 200mcg & 62.5mcg+25mcg DPI Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**For Capsule 1:** Each capsule contains: Fluticasone furoate……..…...100 mcg **For Capsule 2:** Each capsule contains: Umeclidinium (as bromide) …….62.5 mcg Vilanterol (as trifenatate) ……25 mcg **Each delivered dose contains:** Fluticasone furoate……..…...92 mcg Umeclidinium (as bromide) …….55 mcg Vilanterol (as trifenatate) ……22 mcg

	Pharmaceutical form of applied drug	DPI (Dry Powder Inhaler) Capsule
	Pharmacotherapeutic Group of (API)	Fluticasone furoate is an inhaled corticosteroid that can be used as maintenance treatment of asthma and/or chronic obstructive pulmonary disease (COPD) depending on the product. Umeclidinium is a long-acting muscarinic antagonist and Vilanterol is a selective long-acting β2-agonist.
	Reference to Finished product specifications	As per Innovator's Specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	"TRELEGY ELLIPTA" (fluticasone furoate, umeclidinium, and vilanterol inhalation powder) for oral inhalation use" (US-FDA Approved)
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	Last inspection report dated 16.08.2022 concluded good level of cGMP compliance.
	Name and address of API manufacturer.	**Fluticasone Furoate:** VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA). **Umeclidinium Bromide:** Inke, S.A. Area Industrial del Llobregat C/Argent, 1 08755 Castellbisbal, Barcelona- Spain. **Vilanterol Trifenatate:** Inke, S.A. Area Industrial del Llobregat C/Argent, 1 08755 Castellbisbal, Barcelona- Spain.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Reference product that is Trelegy Ellipta Inhalation Powder by performing quality tests (Identification, Water contents, Foreign Particulate Matter, Assay, Delivered dose uniformity, Aerodynamic particle size distribution and Microbial Test. As the applied drug product is Dry Powder inhaler Capsule for inhalational use, So CDP is not required.
	Analytical method validation/verification of product	Analytical method verification studies of both drug substances and Analytical Method Validation Studies have been submitted including Introduction, Verification/Validation of Assay method, Specificity, Accuracy, Precision, Linearity concentration and peak range.
STABILITY STUDY DATA		
Manufacturer of API		**Fluticasone Furoate:** VAMSI LABS LTD. **Umeclidinium Bromide:** Inke, S.A.

		Vilanterol Trifenatate: Inke, S.A.	
API Lot No.		**Fluticasone Furoate:** FTF (P)-0010121 **Umeclidinium Bromide:** PP-15M **Vilanterol Trifenatate:** P-12M	
Description of Pack (Container closure system)		60's Capsules packed in unit carton along with leaflet.	
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH	
Time Period		Real time: 6 months Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 8, 12, 16, 18, 24 (Months)	
Batch No.		FVL-001	FVL-002
Batch Size		Capsule 1: 5000 Capsules Capsule 2: 5000 Capsules	Capsule 1: 5000 Capsules Capsule 2: 5000 Capsules
Manufacturing Date		08– 2023	08– 2023
No. of Batches		02	
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of this product: XETINE 10mg Tablet, (Vortioxetine as Hydrobromide) which was conducted on dated 06-07-2020 and was presented in 313th meeting of Registration Board held on 16-18 Nov, 2021. Registration Board decided to approve registration of XETINE 10mg Tablet, (Vortioxetine as Hydrobromide) by M/s. Horizon Healthcare (Pvt) Ltd. Plot No. 35-A, Small industrial Estate, Taxila, Pakistan. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following observations were reported in the report: iv. The HPLC software is 21 CFR compliant. v. Audit trail on the testing reports of XETINE 10mg Tablet, is available. vi. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.	
2.	Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm had provided valid GMP & Certificate of VAMSI LABS LTD. issued by FDA Maharashtra Valid upto: 04-10-2024	
		Firm had provided valid GMP & Certificate of Inke, S.A. issued by Govt. of Catalonia Valid upto: 27-07-2026	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Clearance Certificate approved by DRAP attested by AD I&E, has been submitted. **Fluticasone Furoate:**	

Batch No.	**Invoice No.**	**Quantity Imported**	**Date of approval by DRAP**
FTF (P)-0010121	EXP/05/21-22	50 grams	30-Sep-2021

		Umeclidinium Bromide: **Batch No.** / **Computerized No.** / **Quantity Imported** / **Date of approval by DRAP** PP-15M / HORIZON02122021 / 50 grams / 17-Sep-2021 **Vilanterol Trifenatate:** **Batch No.** / **Computerized No.** / **Quantity Imported** / **Date of approval by DRAP** P-12M / HORIZON02122021 / 50 grams / 17-Sep-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets have been submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.
Remarks of Evaluator II: Reference product "TRELEGY ELLIPTA" is available as beige plastic inhaler containing 2 foil blister strips. Each blister on one strip contains a white powder blend of micronized fluticasone furoate and each blister on the other strip contains a white powder blend of micronized umeclidinium bromide (74.2 mcg equivalent to 62.5 mcg of umeclidinium), micronized Vilanterol trifenatate (40 mcg equivalent to 25 mcg of vilanterol), magnesium stearate (75 mcg), and lactose monohydrate (12.3 mg). While the firm has replicated this presentation in two separate capsules presented in combo pack and accompanied by a delivery device wherein contents of both capsules can be administered simultaneously.		
Decision: Registration Board deferred the application for clarification of dose delivery mechanism against the innovator product along with details of delivery device to be accompanied with the applied product.		
73.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	Evidence of approval of required manufacturing facility	Firm has submitted copy of section approval letter issued by Secretary CLB wherein grant of following sections has been declared: • Dry Powder for In11alation Section • Solution for Inhalation Section • Ear/Eye Drops-II (General) Section
	GMP status of the Finished product manufacturer	Last inspection report dated 16.08.2022 concluded good level of cGMP compliance.
	Dy. No. and date of submission Details of fee submitted	Tracking ID# J6N-SR4-HVQJ, 29-01-2024 Rs.30,000/- dated 25-09-2023
	The proposed proprietary name / brand name	**Flutrolz 250mcg/50mcg DPI Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Fluticasone Propionate … 250mcg Salmeterol (as xinafoate) … 50mcg Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains 231mcg of Fluticasone Propionate 47mcg of Salmeterol (as xinafoate)
	Pharmaceutical form of applied drug	DPI (dry powder Inhaler) Capsule
	Pharmacotherapeutic Group of (API)	Budesonide Belongs to Glucocorticoids, and Formoterol Fumarate is a long-acting and selective sympathomimetic beta-receptor agonist with bronchodilator activity.
	Reference to Finished product specifications	As per innovator's specs.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	"ADVAIR DISKUS" 500/50 mcg (fluticasone propionate 500 mcg and salmeterol 50 mcg inhalation powder) (US-FDA Approved)
	For generic drugs (me-too status)	Forsonide 500mcg/50mcg DPI Capsule of Pharm-Evo (Pvt.) Ltd. (Reg # 114402)
	Name and address of API manufacturer.	**Salmeterol Xinafoate:** VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA). **Formoterol Fumarate:** VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of both drug substances and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted details of General information, General properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system

		and stability studies of both drug substances.	
	Stability studies	**Stability study conditions:** **Fluticasone Propionate** Real time: 30°C ± 2°C / 65% ± 5% RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months **Salmeterol Xinafoate:** Real time: 30°C ± 2°C / 65% ± 5% RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months	
	Module-III (Drug Product):	The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis , reference standard, Container closure and stabilities studies.	
	Pharmaceutical equivalence	Pharmaceutical Equivalence have been established against the Reference product that is Seretide Diskus 250mcg/50mcg (Powder for Inhalation) of GSK	
	Analytical method validation/verification of product	Analytical method verification studies of both drug substances and Analytical Method Validation Studies have been submitted including Introduction, Verification/Validation of Assay method, Specificity, Accuracy, Precision, Linearity concentration and peak range.	
STABILITY STUDY DATA			
API Lot No.		**Fluticasone Propionate:** FTP-0120821 **Salmeterol Xinafoate:** SX-0070721	
Description of Pack (Container closure system)		30's Capsules packed in unit carton along with leaflet.	
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH	
Time Period		Real time: 6 months Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.		FSM-001	FSM-002
Batch Size		5000 Capsules	5000 Capsules
Manufacturing Date		01– 2023	01– 2023
No. of Batches		02	
74.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.**	
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan	
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of approval of required manufacturing facility	Firm has submitted copy of section approval letter issued by Secretary CLB wherein grant of following sections has been declared: • Dry Powder for In11alation Section • Solution for Inhalation Section • Ear/Eye Drops-II (General) Section
	GMP status of the Finished product manufacturer	Last inspection report dated 16.08.2022 concluded good level of cGMP compliance.
	Dy. No. and date of submission Details of fee submitted	Tracking ID# BD6-515-DBUL, 29-01-2024 Rs.30,000/- dated 25-09-2023
	The proposed proprietary name / brand name	**Flutrolz 500mcg/50mcg DPI Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Fluticasone Propionate … 500mcg Salmeterol (as xinafoate) … 50mcg Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains 460mcg of Fluticasone Propionate 47mcg of Salmeterol (as xinafoate)
	Pharmaceutical form of applied drug	DPI (dry powder Inhaler) Capsule
	Pharmacotherapeutic Group of (API)	Budesonide Belongs to Glucocorticoids, and Formoterol Fumarate is a long-acting and selective sympathomimetic beta-receptor agonist with bronchodilator activity.
	Reference to Finished product specifications	As per innovator's specs.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	"ADVAIR DISKUS" 500/50 mcg (fluticasone propionate 500 mcg and salmeterol 50 mcg inhalation powder) (US-FDA Approved)
	For generic drugs (me-too status)	Forsonide 500mcg/50mcg DPI Capsule of Pharm-Evo (Pvt.) Ltd. (Reg # 114402)
	Name and address of API manufacturer.	**Salmeterol Xinafoate:** VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA). **Formoterol Fumarate:** VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of both drug substances and drug product is submitted.

	Module III (Drug Substance)	The firm has submitted details of General information, General properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of both drug substances.	
	Stability studies	**Stability study conditions:** **Fluticasone Propionate** Real time: 30˚C ± 2˚C / 65% ± 5% RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months **Salmeterol Xinafoate:** Real time: 30˚C ± 2˚C / 65% ± 5% RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months	
	Module-III (Drug Product):	The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis , reference standard, Container closure and stabilities studies.	
	Pharmaceutical equivalence	Pharmaceutical Equivalence have been established against the Reference product that is Seretide Diskus 500mcg/50mcg (Powder for Inhalation) of GSK	
	Analytical method validation/verification of product	Analytical method verification studies of both drug substances and Analytical Method Validation Studies have been submitted including Introduction, Verification/Validation of Assay method, Specificity, Accuracy, Precision, Linearity concentration and peak range.	
STABILITY STUDY DATA			
API Lot No.		**Fluticasone Propionate:** FTP-0120821 **Salmeterol Xinafoate:** SX-0070721	
Description of Pack (Container closure system)		30’s Capsules packed in unit carton along with leaflet.	
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH	
Time Period		Real time: 6 months Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.		FSH-001	FSH-002
Batch Size		5000 Capsules	5000 Capsules
Manufacturing Date		01– 2023	01– 2023
No. of Batches		02	
75.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.**	
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan	
	Status of the applicant	☒ Manufacturer	

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of approval of required manufacturing facility	Firm has submitted copy of section approval letter issued by Secretary CLB wherein grant of following sections has been declared: • Dry Powder for In11alation Section • Solution for Inhalation Section • Ear/Eye Drops-II (General) Section
	GMP status of the Finished product manufacturer	Last inspection report dated 16.08.2022 concluded good level of cGMP compliance.
	Dy. No. and date of submission Details of fee submitted	Tracking ID# 25763, 25-10-2023 Rs.30,000/- dated 25-09-2023
	The proposed proprietary name / brand name	**Flutrolz 100mcg/50mcg DPI Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Fluticasone Propionate … 100mcg Salmeterol (as xinafoate) … 50mcg Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains 92mcg of Fluticasone Propionate 47mcg of Salmeterol (as xinafoate)
	Pharmaceutical form of applied drug	DPI (dry powder Inhaler) Capsule
	Pharmacotherapeutic Group of (API)	Budesonide Belongs to Glucocorticoids, and Formoterol Fumarate is a long-acting and selective sympathomimetic beta-receptor agonist with bronchodilator activity.
	Reference to Finished product specifications	As per innovator's specs.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	"ADVAIR DISKUS" 100/50 mcg (fluticasone propionate 100 mcg and salmeterol 50 mcg inhalation powder) (US-FDA Approved)
	For generic drugs (me-too status)	Forsonide 100mcg/50mcg DPI Capsule of Pharm-Evo (Pvt.) Ltd. (Reg # 114400)
	Name and address of API manufacturer.	**Salmeterol Xinafoate:** VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA). **Formoterol Fumarate:** VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers,

		description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of both drug substances and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted details of General information, General properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of both drug substances.
	Stability studies	**Stability study conditions:** **Fluticasone Propionate** Real time: 30˚C ± 2˚C / 65% ± 5% RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months **Salmeterol Xinafoate:** Real time: 30˚C ± 2˚C / 65% ± 5% RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis , reference standard, Container closure and stabilities studies.
	Pharmaceutical equivalence	Pharmaceutical Equivalence have been established against the Reference product that is Seretide Diskus 100mcg/50mcg (Powder for Inhalation) of GSK
	Analytical method validation/verification of product	Analytical method verification studies of both drug substances and Analytical Method Validation Studies have been submitted including Introduction, Verification/Validation of Assay method, Specificity, Accuracy, Precision, Linearity concentration and peak range.

STABILITY STUDY DATA		
API Lot No.	**Fluticasone Propionate:** FTP-0120821 **Salmeterol Xinafoate:** SX-0070721	
Description of Pack (Container closure system)	30’s Capsules packed in unit carton along with leaflet.	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	FSL-001	FSL-002
Batch Size	5000 Capsules	5000 Capsules
Manufacturing Date	01– 2023	01– 2023
No. of Batches	02	
Administrative Portion		

<table>
<tr><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td>Firm has referred to onsite inspection report of this product:

XETINE 10mg Tablet, (Vortioxetine as Hydrobromide)

which was conducted on dated 06-07-2020 and was presented in 313th meeting of Registration Board held on 16-18 Nov, 2021.
Registration Board decided to approve registration of
XETINE 10mg Tablet, (Vortioxetine as Hydrobromide)
by M/s. Horizon Healthcare (Pvt) Ltd. Plot No. 35-A,
Small industrial Estate, Taxila, Pakistan. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
Following observations were reported in the report:
i. The HPLC software is 21 CFR compliant.
ii. Audit trail on the testing reports of XETINE 10mg Tablet, is available.
iii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.</td></tr>
<tr><td>Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>GMP certificate of M/s VAMSI LABS LTD. is submitted, issued by FDA valid upto: 04-10-2024</td></tr>
<tr><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of Clearance Certificate approved by DRAP attested by AD I&E, has been submitted.

Fluticasone Propionate:
<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>SX-0070721</td><td>EXP/210/21-22</td><td>25.00 grams</td><td>29-Aug-2022</td></tr></table>
Salmeterol Xinafoate:
<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>FTP-0120821</td><td>EXP/210/21-22</td><td>25.00 grams</td><td>29-Aug-2022</td></tr></table></td></tr>
<tr><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets have been submitted.</td></tr>
<tr><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing have been submitted.</td></tr>
<tr><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.</td></tr>
<tr><td colspan="2">Remarks of Evaluator II:</td></tr>
</table>

Section #	Observations	Firm's response
3.2.P.5.2	• Evidence of availability of emission spectrophotometer shall be submitted, required for the analysis of Fluticasone in drug product as per USP monograph.	Submitted

- Upon observation regarding product development prior to the section approval firm has referred to the panel inspection report dated 10-08-2022 & 16-08-2022, wherein availability of Copley Dry Powder Inhaler (required for testing of DPI products) & R&D lab has been declared.
- Following details of Drug delivery device to be accompanied with applied product has been submitted:

Name: Rotazone Inhaler Device
Manufactured by Shanghai Harui Aerosol Co.LtD No 222,yuanchun road Pudong new district shanghai,201399,P.R.China

Decision: Registration Board approved the applications of Flutrolz 500mcg/50mcg DPI Capsule & Flutrolz 100mcg/50mcg DPI Capsule.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

➢ M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad has been granted new section of "Liquid Injectable Ampoule (General) section" dated 08-11-2022.

76.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 08-11-2022 specifying Liquid Injectable Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 21299 dated 29-08-2023
	Details of fee submitted	Rs.30,000/- dated 23-08-2023
	The proposed proprietary name / brand name	**Tiofrel 4mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains Thiocolchicoside ……. 4mg
	Pharmacotherapeutic Group of (API)	Muscle Relaxants, Centrally Acting Agents ATC Code: M03BX05
	Pharmaceutical form of applied drug	Solution for Injection
	Reference to Finished product specifications	Innovator specifications

	Proposed Pack size	2ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Miorel 4mg/2ml , solution for injection (IM) in ampoule, approved by, ANSM France.
	For generic drugs (me-too status)	Muscoril 4mg/2ml Injection Reg. No. 015501 M/s Sanofi Aventis Pkaistan
	Name and address of API manufacturer.	M/s Dr. Willmar Schwabe India Pvt. Ltd. Plot No. 51-53. Sector 31-B IMT Rohtak Haryana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Muscoril injection.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Dr. Willmar Schwabe India Pvt. Ltd. Plot No. 51-53. Sector 31-B IMT Rohtak Haryana India.
API Lot No.	WS-HH/THIO/22020006

Description of Pack (Container closure system)	Liquid solution filled in glass ampoules		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	12-2022	12-2022	12-2022
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has been inspected for verification of stability study data for following products. a) Dexpro (Dexlansoprazole) 30 and 60mg Capsule approved in 285th meeting of Registration Board. b) Neovel 800mg Tablet approved in 288th meeting of Registration Board. c) Serbica 20mg Capsule approved in 290th meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate issued y Food and Drug administration Haryana, India valid till 09-02-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate no. E-1783786525978 dated 29-06-2022 for Thiocolchicoside 1Kg.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section #	Observations	Firm's response
3.2.S.4.3	• Submit drug substance analytical method verification studies from M/s Seraph Pharmaceutical.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

77.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.**

	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 08-11-2022 specifying Liquid Injectable Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 20057 dated 15-08-2023
	Details of fee submitted	Rs.30,000/- dated 27-07-2023
	The proposed proprietary name / brand name	**DEXMEDA 200mcg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2 ml ampoule contains: Dexmedetomidine as HCl …… 200 mcg
	Pharmacotherapeutic Group of (API)	Miscellaneous anxiolytics, sedatives and hypnotics.
	Pharmaceutical form of applied drug	Solution for injection
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved in USFDA
	For generic drugs (me-too status)	Precedex® Injection, Registration # 88249.
	Name and address of API manufacturer.	M/s Shandong Chenghui Shuangda Pharmaceutical Co., Ltd. Economic Development Zone , Pingyuan County, Dezhou City, Shandong Province253100，China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Firm has submitted stability study data of 2 batches

	(Conditions & duration of Stability studies)	of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Shandong Chenghui Shuangda Pharmaceutical Co., Ltd. Economic Development Zone , Pingyuan County, Dezhou City, Shandong		
API Lot No.	028221101		
Description of Pack (Container closure system)	Liquid solution filled in glass ampoules		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	
Batch Size	2000 ampoules	2000 ampoules	
Manufacturing Date	01-2023	01-2023	
Date of Initiation	01-01-2023	01-01-2023	
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has been inspected for verification of stability study data for following products. a) Dexpro (Dexlansoprazole) 30 and 60mg Capsule approved in 285th meeting of Registration Board. b) Neovel 800mg Tablet approved in 288th meeting of Registration Board. c) Serbica 20mg Capsule approved in 290th meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate This certificate specifies that the firm is operating at satisfactory level of GMP compliance.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate no. E-4118386527812 dated 10-01-2023 for Dexmedetomidine 6gm.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section #	Observations	Firm's response
2.3.R.1.1	• Submit complete batch manufacturing record for stability batches.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

78.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 08-11-2022 specifying Liquid Injectable Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 21300 dated 29-08-2023
	Details of fee submitted	Rs.30,000/- dated 24-08-2023
	The proposed proprietary name / brand name	**Ibelac 3mg/3ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 3ml ampoule contains: Ibandronate sodium monohydrate eq. to Ibandronic acid …… 3mg
	Pharmacotherapeutic Group of (API)	Bisphosphonates
	Pharmaceutical form of applied drug	Solution for injection.
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Ibandronate sodium 3mg/3ml injection approved by US FDDA as pre-filled syringe.
	For generic drugs (me-too status)	Adronil Injection 3mg/3ml of M/s Searle Company Limited, Pakistan (Reg.No. 075870)
	Name and address of API manufacturer.	M/s PROVENTUS LIFE SCIENCES PVT., LTD No. C-9, Industrial complex, Maraimalai Nagar-603209,Kancheepuram District.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Firm has submitted pharmaceutical equivalence of their product against the Adronil injection.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s PROVENTUS LIFE SCIENCES PVT., LTD No. C-9, Industrial complex, Maraimalai Nagar-603209,Kancheepuram District.
API Lot No.	IBB09221009
Description of Pack (Container closure system)	Liquid solution filled in glass ampoules

Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	01-2023	01-2023	01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has been inspected for verification of stability study data for following products. a) Dexpro (Dexlansoprazole) 30 and 60mg Capsule approved in 285th meeting of Registration Board. b) Neovel 800mg Tablet approved in 288th meeting of Registration Board. c) Serbica 20mg Capsule approved in 290th meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate issued by Drug Control Chennai valid upto 31-12-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate no. E-250986525687 dated 07-03-2022 for Ibandronic sodium monohydrate 2Kg.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section #	Observations	Firm's response
1.5.9	• Submit evidence of approval of applied formulation by reference regulatory authorities in " Glass Ampoule"	Approved by EMA as PFS
3.2.P.8.3	• Submit complete batch manufacturing record for stability batches.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

- M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore has been granted new section of "Eye Drop (general section)" dated 14-10-2020.

79.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore
	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)
	GMP status of the firm	Firm has submitted copy of letter of grant of additional section dated 14-10-2020 specifying Eye Drop (general section)
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 14-10-2020 specifying Eye Drop (general section)
	Dy. No. and date of submission	Dy.No 22331 dated 11-09-2023
	Details of fee submitted	Rs.30,000/- dated 07-09-2023
	The proposed proprietary name / brand name	**Nevacan 1mg/ml Opthalmic Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Nepafenac …….1mg
	Pharmaceutical form of applied drug	Sterile Ophthalmic suspension
	Pharmacotherapeutic Group of (API)	Ophthalmological, Anti-inflammatory agents, non-steroids.
	Reference to Finished product specifications	Innovator's Specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Nevanac 0.1% opthalmic suspension of M/s Ali Gohar & Company (Reg.#047563)
	Name and address of API manufacturer.	M/s Precise Bio-Pharma Pvt. Limited. Manufacturing: C 384, TTC Industrial Area, Pawane MIDC, Navi Mumbai - 400 703, Maharashtra, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5%.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established Nevanac Opthalmic suspension.
	Analytical method validation/verification of product	Method validation studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA		
Manufacturer of API	M/s Precise Bio-Pharma Pvt. Limited. Manufacturing: C 384, TTC Industrial Area, Pawane MIDC, Navi Mumbai - 400 703, Maharashtra, INDIA.	
API Lot No.	075005062022.	
Description of Pack (Container closure system)	LDPE bottle with polypropylene dropping nozzle with HDPE Cap.	
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0 ,3,6 (Months) Real Time: 0 , 3,6 (Months)	
Batch No.	T01	T02
Batch Size	2,000 packs	2,000 packs
Manufacturing Date	05-2023	05-2023
No. of Batches	02	

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML no. MH/104764 issued by FDA Maharashtra India valid till 05-09-2027.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Licene to import no. K-1744642845691 issued by AD I&E Lahore dated 10-04-2023 along with commercial invoice for import of 25gm of Nepafenac.

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

Remarks of Evaluator:

Section #	Observations	Firm's response
3.2.P.8.3	• Submit stability studies data of drug product trial batches for 6th month time point. • Submit complete batch manufacturing record of stability batches.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

80.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore
	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)
	GMP status of the firm	Firm has submitted copy of letter of grant of additional section dated 14-10-2020 specifying Eye Drop (general section)
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 14-10-2020 specifying Eye Drop (general section)
	Dy. No. and date of submission	Dy.No 25791 dated 25-10-2023
	Details of fee submitted	Rs.30,000/- dated 13-09-2023
	The proposed proprietary name / brand name	**Nestar 0.2mg/ml Opthalmic Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Netarsudil as Dimesylate …….. 0.2mg
	Pharmaceutical form of applied drug	Sterile Ophthalmic Solution.
	Pharmacotherapeutic Group of (API)	Rho kinase inhibitor
	Reference to Finished product specifications	Innovator's Specifications.

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	RHOPRESSA 0.02% opthalmic solution approved by US FDA
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Yibin Hongguang Pharmaceutical Co. Ltd Luolong Street, Nanxi District Yibin, Sichuan, 644002 China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of both drug substances at both accelerated as well as real time conditions. The accelerated stability data is conducted at (5 °C ± 3 °C). The real time stability data is conducted at (-20°C ±5°C).
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established Rhopressa eye drops of M/s Alcon.
	Analytical method validation/verification of product	Method validation studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Yibin Hongguang Pharmaceutical Co. Ltd Luolong Street, Nanxi District Yibin, Sichuan, 644002 China.
API Lot No.	MS104901-230101
Description of Pack (Container closure system)	LDPE bottle with polypropylene dropping nozzle with HDPE Cap.
Stability Storage Condition	Real time: 5°C ± 3°C Accelerated: 25°C ± 2°C;40% RH ±5%
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0 ,3,6 (Months) Real Time: 0 , 3,6 (Months)	
Batch No.	T01	T02
Batch Size	2,000 packs	2,000 packs
Manufacturing Date	05-2023	05-2023
No. of Batches	02	

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Section #	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate of drug substance manufacturer, issued by relevant regulatory authority of country of origin.	Firm has submitted copy of DML No. 20170447 for M/s Yibin Hongguang Pharmaceutical Co., Ltd valid till 29-12-2025.
3.2.P.8.3	• Submit stability studies data of drug product trial batches for 6th month time point. • Submit documents confirming import of drug substance. • Submit complete batch manufacturing record of stability batches.	• Firm has submitted stability data for 6th month time point. • Firm has submitted Licene to import no. K-1702942845739 issued by AD I&E Lahore dated 27-03-2023 along with commercial invoice for import of 15gm of Netarsudil. • BMR for stability batches submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

81.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind**

		road, Lahore
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore
	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)
	GMP status of the firm	Firm has submitted copy of letter of grant of additional section dated 14-10-2020 specifying Eye Drop (general section)
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 14-10-2020 specifying Eye Drop (general section)
	Dy. No. and date of submission	Dy.No 25791 dated 25-10-2023
	Details of fee submitted	Rs.30,000/- dated 13-09-2023
	The proposed proprietary name / brand name	**Latano-T Opthalmic Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Latanoprost…0.05mg Timolol as Maleate…5mg
	Pharmaceutical form of applied drug	Sterile Ophthalmic Solution.
	Pharmacotherapeutic Group of (API)	**Latanoprost:** Ophthalmologicals, antiglaucoma preparations and miotics, prostaglandin analogues. ATC code: S01EE01. **Timolol**: nonselective beta-adrenergic receptor blocker.
	Reference to Finished product specifications	Innovator's Specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xalacom 0.05 mg/ml & 5 mg/ml Eye drops, solution Approved by MHRA of UK
	For generic drugs (me-too status)	Xalacom eye drops of M/s Pfizer (Reg.# 031386)
	Name and address of API manufacturer.	Latanoprost: M/s Cayman Pharma. **Address:** ul. Práce 657, 277 11 Neratovice, Czech Republic **Timolol Maleate:** M/s FDC Limited, Plot No.19 & 20/2, M.I.D.C Industrial Area, Village Dhatav, Roha-402 116, District Raigad, Maharashtra State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug

		product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of both drug substances at both accelerated as well as real time conditions. Latanoprost: The accelerated stability data is conducted at 5°C ± 3°C / 75% ± 5% RH. The real time stability data is conducted at -20°C ± 5°C. Timolol maleate: The accelerated stability data is conducted at 40° ± 2°C / 75% ± 5% RH. The real time stability data is conducted at 30°C + 2 °C / 65 ± 5% RH.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established Xalacom eye drops of M/s Pfizer.
	Analytical method validation/verification of product	Method validation studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Latanoprost: M/s Cayman Pharma. **Address:** ul. Práce 657, 277 11 Neratovice, Czech Republic **Timolol Maleate:** M/s FDC Limited, Plot No.19 & 20/2, M.I.D.C Industrial Area, Village Dhatav, Roha-402 116, District Raigad, Maharashtra State, India.	
API Lot No.	Latanoprost: 2008S004. Timolol: 021D026	
Description of Pack (Container closure system)	LDPE bottle with polypropylene dropping nozzle with HDPE Cap.	
Stability Storage Condition	Real time: 5°C ± 3°C Accelerated: 25°C ± 2°C;40% RH ±5%	
Time Period	Real time: 24 months Accelerated: 6 months	
Frequency	Accelerated: 0 , 3,6 (Months) Real Time: 0 , 3,6 (Months)	
Batch No.	T01	T02
Batch Size	2,000 packs	2,000 packs
Manufacturing Date	11/2022	11/2022
No. of Batches	02	

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Latanoprost: Firm has submitted copy of EUdra GMP certificate no. "sukls1L6019/2022" valid till 27-07-2025. Timolol: Firm has submitted copy of GMP certificate no." NEW-WHO-GMP/CERTIKD/104350/2021/11/3716" valid till 03-09-2024 issued by FDA Maharashtra India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Latanoprost:** Firm has submitted loan letter of Latanoprost 3.5gm from Pacific Pharmaceuticals Ltd., dated: 12-08-2022 With copy of ADC attested commercial invoice dated: 24-02-2021 in name of Pacific Pharmaceuticals Ltd. from M/s Cayman Pharma. **Timolol:** Firm has submitted loan letter of Timolol maleate from Pacific Pharmaceuticals Ltd., dated: 12-08-2022 With copy of ADC attested commercial invoice dated: 04-02-2022 in name of Pacific Pharmaceuticals Ltd. from M/s FDC Ltd.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
82.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore
	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)
	GMP status of the firm	Firm has submitted copy of letter of grant of additional section dated 14-10-2020 specifying Eye Drop (general section)

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 14-10-2020 specifying Eye Drop (general section)
	Dy. No. and date of submission	Dy.No 26507 dated 02-11-2023
	Details of fee submitted	Rs.30,000/- dated 13-09-2023
	The proposed proprietary name / brand name	**Latano Ophthalmic Solution 0.005%.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Ophthalmic Solution containing: Latanoprost……0.05 mg.
	Pharmaceutical form of applied drug	Sterile Ophthalmic Solution.
	Pharmacotherapeutic Group of (API)	Prostaglandin F2α analogue.
	Reference to Finished product specifications	Innovator's Specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Xalatan eye drops of M/s Pfizer (Reg.# 021125)
	Name and address of API manufacturer.	M/s Cayman Pharma. **Address:** ul. Práce 657, 277 11 Neratovice, Czech Republic
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 5°C ± 3°C / 75% ± 5% RH. The real time stability data is conducted at -20°C ± 5°C.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established Xalatan eye drops of M/s Pfizer.
	Analytical method validation/verification of	Method validation studies have submitted including

	product	accuracy, precision, specificity.

STABILITY STUDY DATA		
Manufacturer of API	M/s Cayman Pharma. **Address:** ul. Práce 657, 277 11 Neratovice, Czech Republic	
API Lot No.	2008S004.	
Description of Pack (Container closure system)	LDPE bottle with polypropylene dropping nozzle with HDPE Cap.	
Stability Storage Condition	Real time: 5°C ± 3°C Accelerated: 25°C ± 2°C;40% RH ±5%	
Time Period	Real time: 24 months Accelerated: 6 months	
Frequency	Accelerated: 0 , 3,6 (Months) Real Time: 0 , 3,6 (Months)	
Batch No.	T001	T002
Batch Size	2,000 packs	2,000 packs
Manufacturing Date	09/2022	09/2022
No. of Batches	02	

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of EUdra GMP certificate no. "sukls1L6019/2022" valid till 27-07-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Latanoprost:** Firm has submitted loan letter of Latanoprost 3.5gm from Pacific Pharmaceuticals Ltd., dated: 12-08-2022 With copy of ADC attested commercial invoice dated: 24-02-2021 in name of Pacific Pharmaceuticals Ltd. from M/s Cayman Pharma.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

- M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore has been granted new section of "Tablet (Psychotropic section)" dated 14-10-2020.

83.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore
	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)
	GMP status of the firm	Firm has submitted copy of letter of grant of additional section dated 14-10-2020 specifying Tablet (Psychotropic section)
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 14-10-2020 specifying Tablet (Psychotropic section)
	Dy. No. and date of submission	Dy.No 21516 dated 31-08-2023
	Details of fee submitted	Rs.30,000/- dated 31-08-2023
	The proposed proprietary name / brand name	**Alzam 0.25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Alprazolam ……. 0.25mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anxiolytic.
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Xanax tablet of M/s Pfizer (Reg.#014417)
	Name and address of API manufacturer.	M/s Lake Chemicals Private Limited., 21-M, Attibele Industrial Area, Anekal Taluk, Bangalore-562107, Karnataka (India).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5%.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence & CDP studies have been submitted against Xanax 0.25mg tablet of M/s Pfizer
	Analytical method validation/verification of product	Method validation studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Lake Chemicals Private Limited., 21-M, Attibele Industrial Area, Anekal Taluk, Bangalore-562107, Karnataka (India).		
API Lot No.	802022003A.		
Description of Pack (Container closure system)	Aluminum / Aluminum blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	5,000 Tablets	5,000 Tablets	5,000 Tablets
Manufacturing Date	11/2022.	11/2022.	11/2022.
No. of Batches	02		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted valid CEP certificate no. R1-CEP 2008-229 - Rev 03 issued by EDQM for bromaxepam in name of M/s Lake Chemicals Private Limited.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	➢ Firm has submitted Licene to import no. K-3146642849182 issued by AD I&E Lahore dated 13-04-2022 along with commercial invoice for import of 38gm of Alprazolam ➢ Firm has submitted letter no. F.5-2/2021-REG-II (M-307) dated 09-09-2021 from Assistant Director (Reg-I) for approval by Registration Board for allocation of controlled drugs including Alprazolam.

		➢ Firm has submitted letter no. F.5-5/2021-CD (M-77) dated 13-12-2021 from Deputy Director (CD) granting import authorization no. P.No. 338/2021-CD for 38gm of Alprazolam.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Section #	Observations	Firm's response
3.2.P.5.4	• Submit results of dosage uniformity test by way of content uniformity	Submitted
3.2.P.8.3	• Submit complete batch manufacturing record of stability batches. • Submit record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

84.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore
	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)
	GMP status of the firm	Firm has submitted copy of letter of grant of additional section dated 14-10-2020 specifying Tablet (Psychotropic section)
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 14-10-2020 specifying Tablet (Psychotropic section)
	Dy. No. and date of submission	Dy.No 22052 dated 07-09-2023
	Details of fee submitted	Rs.30,000/- dated 05-09-2023

	The proposed proprietary name / brand name	**Bromlet 3mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Bromazepam…….3mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anxiolytic.
	Reference to Finished product specifications	Innovator's Specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by HPRA of Ireland
	For generic drugs (me-too status)	Azonil 3 mg tablet of M/s Global (Reg.#041540)
	Name and address of API manufacturer.	M/s Lake Chemicals Private Limited., 21-M, Attibele Industrial Area, Anekal Taluk, Bangalore-562107, Karnataka (India).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5%.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence & CDP studies have been submitted against Lexotanil 3mg tablet.
	Analytical method validation/verification of product	Method validation studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Lake Chemicals Private Limited., 21-M, Attibele Industrial Area, Anekal Taluk, Bangalore-562107, Karnataka (India).
API Lot No.	802022003A.

Description of Pack (Container closure system)	Aluminum / Aluminum blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	5,000 Tablets	5,000 Tablets	5,000 Tablets
Manufacturing Date	11/2022.	11/2022.	11/2022.
No. of Batches	02		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted valid CEP certificate no. R1-CEP 2010-053 - Rev 00 issued by EDQM for Bromazepam in name of M/s Lake Chemicals Private Limited.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	➢ Firm has submitted Licene to import no. K-3146642849182 issued by AD I&E Lahore dated 13-04-2022 along with commercial invoice for import of 58gm of Bromazepam ➢ Firm has submitted letter no. F.5-2/2021-REG-II (M-307) dated 09-09-2021 from Assistant Director (Reg-I) for approval by Registration Board for allocation of controlled drugs including Bromazepam. ➢ 4.Firm has submitted letter no. F.5-5/2021-CD (M-77) dated 13-12-2021 from Deputy Director (CD) granting import authorization no. P.No. 339/2021-CD for 58gm of Bromazepam.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Section #	Observations	Firm's response
3.2.S.4.3	• Submit analytical method verification studies for drug substance by M/s Cunningham	Submitted
3.2.P.6	• COA of reference/working standard used for analysis of stability batches shall be submitted.	Submitted

	3.2.P.8.3	• Submit complete batch manufacturing record of stability batches. • Submit record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

➢ M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi has been granted new section of "Dry Powder Injection Cephalosporin" dated 29-04-2022.

85.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 20829 dated 23-08-2023
	Details of fee submitted	Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Ceftizime 1gm IV/IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftizoxime Soidum Eq. to Ceftizoxime…1gm
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Dry powder for injection
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefizox 1g Injection (Baxter Health Care- Deerfield) (Discontinued in USFDA Approved)
	For generic drugs (me-too status)	Cefizox 1g Injection of M/s Barrette Hodgsone Pakistan pvt Ltd. (Reg.No. 008415)

	Name and address of API manufacturer.	Akum Life Sciences Limited Unit I : VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH f The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Cefizox 1g manufactured by Barretee Hodgson Pakistan Pvt Lt
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Akum Life Sciences Limited Unit I : VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)
API Lot No.	CFS/003/17, CFS/005/17, CFS/007/17
Description of Pack (Container closure system)	Vial
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-101	IB-103	CF-105
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. Pb.2021/4570) dated 19-07-2021, issued by Food & Drugs Administration Punjab India. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	--
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	--
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	--

Remarks of Evaluator:

- Following shall be submitted:

  i. Evidence of approval of applied formulation by reference regulatory authorities adopted by Registration Board in its 275th meeting, since submitted reference product has been declared as Discontinued by US FDA.
  ii. Analytical record of stability studies supported by respective documents like chromatograms, COA etc..
  iii. Compliance Record of HPLC software 21CFR & audit trail reports on product testing
  iv. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).
  v. Documents confirming procurement of drug substance.
  vi. Complete batch manufacturing record for three stability batches shall be submitted.

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

86.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 20834 dated 23-08-2023
	Details of fee submitted	Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Cefuxime 1.5g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefuroxime Sodium Equivalent to Cefuroxime.....1.5mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Dry powder for injection
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zinacef 250mg Injection (USFDA Approved)
	For generic drugs (me-too status)	Zinacef 250mg Injection of M/s Glaxo Smith Kline, (Reg.No. 006221)
	Name and address of API manufacturer.	Akum Life Sciences Limited Unit I : VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Zinacef 1.5g manufactured by Glaxo SmithKline
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Akum Life Sciences Limited Unit I : VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)		
API Lot No.	CFR/032/15, CFR/035/15, CFR/039/15		
Description of Pack (Container closure system)	Vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-031	IB-032	IB-033
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	15-02-2022	16-02-2022	17-02-2022
No. of Batches	03		

87.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 20833 dated 23-08-2023
	Details of fee submitted	Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Cefuxime 750mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefuroxime Sodium Equivalent to Cefuroxime.....750mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Dry powder for injection
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zinacef 250mg Injection (USFDA Approved)
	For generic drugs (me-too status)	Zinacef 250mg Injection of M/s Glaxo Smith Kline, (Reg.No. 006221)
	Name and address of API manufacturer.	Akum Life Sciences Limited Unit I : VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials,

		container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Zinacef 750mg manufactured by Glaxo SmithKline
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Akum Life Sciences Limited Unit I : VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)		
API Lot No.	CFR/032/15, CFR/035/15, CFR/039/15		
Description of Pack (Container closure system)	Vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-025	IB-026	IB-027
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	08-02-2022	10-02-2022	12-02-2022
No. of Batches	03		

88.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 20822 dated 23-08-2023
	Details of fee submitted	Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Cefuxime 250mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains:

		Cefuroxime Sodium Equivalent to Cefuroxime.....250mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Dry powder for injection
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zinacef 250mg Injection (USFDA Approved)
	For generic drugs (me-too status)	Zinacef 250mg Injection of M/s Glaxo Smith Kline, (Reg.No. 006221)
	Name and address of API manufacturer.	Akum Life Sciences Limited Unit I : VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Zinacef 250mg manufactured by Glaxo SmithKline
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug

		product.

STABILITY STUDY DATA

Manufacturer of API	Akum Life Sciences Limited Unit I : VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)		
API Lot No.	CFR/032/15, CFR/035/15, CFR/039/15		
Description of Pack (Container closure system)	Vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-020	IB-021	IB-022
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	02-02-2022	04-02-2022	07-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. Pb.2021/4570) dated 19-07-2021, issued by Food & Drugs Administration Punjab India. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	--
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	--
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	--

Remarks of Evaluator:

- Following shall be submitted:

  i. Analytical record of stability studies supported by respective documents like chromatograms, COA etc..
  ii. Compliance Record of HPLC software 21CFR & audit trail reports on product testing
  iii. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).
  iv. Documents confirming procurement of drug substance.

v.	Compete batch manufacturing record for three stability batches shall be submitted.	
Decision: Registration Board deferred the applications of Cefuxime 1.5g Injection, Cefuxime 750mg Injection & Cefuxime 250mg Injection fo submission of reply to the above cited shortcomings.		
89.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 20828 dated 23-08-2023 Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Certazone 2g Injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftriaxone Sodium Equivalent to Ceftriaxone.....2g
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Almost white or yellowish crystalline powder.
	Reference to Finished product specifications	(USP Specification)
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Cefzect 2gm Injection IV of M/s Nicholas (Reg.No. 094293)
	Name and address of API manufacturer.	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Cefxone 2g IV manufactured by Bosch Pharmaceuticals PVT Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore		
API Lot No.	00421/010/2022		
Description of Pack (Container closure system)	Glass Vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-091	IB-093	IB-095
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
No. of Batches	03		

90.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 20845 dated 23-08-2023 Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Certazone 1g Injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftriaxone Sodium Equivalent to Ceftriaxone.....1g
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Almost white or yellowish crystalline powder.
	Reference to Finished product specifications	(USP Specification)
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Rochephin 1gm Injection IV of M/s Roche Pakistan, Karachi (Reg.No. 007014)
	Name and address of API manufacturer.	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Rocephin 1 g IV manufactured by Roche
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore		
API Lot No.	00421/010/2022		
Description of Pack (Container closure system)	Glass Vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-001	IB-002	IB-003
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
No. of Batches	03		

91.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 20831 dated 23-08-2023 Rs.30,000/- dated 16-09-2022

	The proposed proprietary name / brand name	**Certazone 1g Injection IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftriaxone Sodium Equivalent to Ceftriaxone.....1g
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Almost white or yellowish crystalline powder.
	Reference to Finished product specifications	(USP Specification)
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Rochephin1gm Injection IM of M/s Roche Pakistan, Karachi (Reg.No. 008436)
	Name and address of API manufacturer.	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Rocephin 1 g IM manufactured by Roche

	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore		
API Lot No.	00421/010/2022		
Description of Pack (Container closure system)	Glass Vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-001	IB-002	IB-003
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
No. of Batches	03		

92.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 20823 dated 23-08-2023 Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Certazone 500mg Injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftriaxone Sodium Equivalent to Ceftriaxone.....500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Almost white or yellowish crystalline powder.
	Reference to Finished product specifications	(USP Specification)
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved

	For generic drugs (me-too status)	Rochephin 500mg Injection IV of M/s Roche Pakistan, Karachi (Reg.No. 008435)
	Name and address of API manufacturer.	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Titan 500mg IV manufactured by Macter International Limited.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore
API Lot No.	00421/010/2022
Description of Pack (Container closure system)	Glass Vial
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH

		Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		IB-083	IB-085	IB-087
Batch Size		500 Vials	500 Vials	500 Vials
Manufacturing Date		02-2022	02-2022	02-2022
No. of Batches		03		
93.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**		
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi		
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)		
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.		
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)		
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)		
	Dy. No. and date of submission & Details of fee submitted	Dy.No 20846 dated 23-08-2023 Rs.30,000/- dated 16-09-2022		
	The proposed proprietary name / brand name	**Certazone 500mg Injection IM**		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftriaxone Sodium Equivalent to Ceftriaxone.....500mg		
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics		
	Pharmaceutical form of applied drug	Almost white or yellowish crystalline powder.		
	Reference to Finished product specifications	(USP Specification)		
	Proposed Pack size	1's		
	Proposed unit price	As per SRO		
	The status in reference regulatory authorities	USFDA Approved		
	For generic drugs (me-too status)	Rochephin 500mg Injection IM of M/s Roche Pakistan, Karachi (Reg.No. 008434)		
	Name and address of API manufacturer.	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore		
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its		

		validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Rocephin 500mg IM manufactured by Roche
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore		
API Lot No.	00421/010/2022		
Description of Pack (Container closure system)	Glass Vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-063	IB-065	IB-067
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
No. of Batches	03		

94.	**Name, address of Applicant / Marketing**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E.**

	Authorization Holder	**Super Highway Karachi**
	Name, address of Manufacturing site.	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 20844 dated 23-08-2023 Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Certazone 250mg Injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftriaxone Sodium Equivalent to Ceftriaxone.....250mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Almost white or yellowish crystalline powder.
	Reference to Finished product specifications	(USP Specification)
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rocephin 250mg Injection (USFDA Approved)
	For generic drugs (me-too status)	Rochephin 250mg Injection IM of M/s Roche Pakistan, Karachi (Reg.No. 008433)
	Name and address of API manufacturer.	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Inocef 250mg IV manufactured by Barrett Hodgson Pakistan (PVT) Limited.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore		
API Lot No.	00421/010/2022		
Description of Pack (Container closure system)	Glass Vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-045	IB-046	IB-047
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
No. of Batches	03		

95.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 20839 dated 23-08-2023 Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Certazone 250mg Injection IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftriaxone Sodium Equivalent to Ceftriaxone.....250mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Almost white or yellowish crystalline powder.
	Reference to Finished product specifications	(USP Specification)
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rocephin 250mg IM Injection (USFDA Approved)
	For generic drugs (me-too status)	Rochephin 250mg Injection IM of M/s Roche Pakistan, Karachi (Reg.No. 008432)
	Name and address of API manufacturer.	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols,

		control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Titan 250mg IM manufactured by M/s. Macter International Limited.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore		
API Lot No.	00421/010/2022		
Description of Pack (Container closure system)	Glass Vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-075	IB-078	IB-080
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 204/2022 DRAP AD/159531263130-531) dated 22-11-2022 issued by Drug Regulatory Authority of Pakistan. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Applicable
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Remarks of Evaluator:

Section#	Observations	Firm's response

3.2. S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
3.2. S.7	Tests of sterility have not been performed during stability studies. Justification shall be submitted in this regard.	
3.2.P.2.2.1	Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product.	
3.2. P.5	• Justify the specifications of fill weight/vial against the proposed weight of Ceftriaxone sodium per unit vial mentioned in the 3.2.P.1 section. • Specifications does not include test of "Particulate matter", & "Water determination". • Analytical method for Assay does not mentions the chromatographic conditions as per USP monograph. • Sample preparation procedure in the Assay test is not as per the USP monograph for "Ceftriaxone for Injection". • As per submitted record, analytical method verification studies have not been conducted as per chromatographic conditions mentioned in USP Monograph. • As per submitted batch analysis certificates, tests of "Particulate matter", & "Water determination" have not been performed.	•
3.2. P.8	• Justify the specifications of filled weight/vial applied in the stability studies. • Same batch numbers have been assigned to trial batches of Certazone 1gm IM and Cetrazone 1gm IV injections. • Batch manufacturing date declared in stability summary sheets is earlier to the date of grant of additional section of "Dry Powder Injection Cephalosporin" by Licensing Division. Justification shall be submitted in this regard. • Following shall be submitted: i. Analytical record of stability studies supported by respective	•

		documents like chromatograms, COA etc.. ii. Compliance Record of HPLC software 21CFR & audit trail reports on product testing iii. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). iv. Documents confirming procurement of drug substance. v. Compete batch manufacturing record for three stability batches shall be submitted.	

Decision: Registration Board deferred the applications of Certazone 2g Injection IV, Certazone 1g Injection IM, Certazone 1g Injection IV, Certazone 500mg Injection IV, Certazone 500mg Injection IM, Certazone 250mg Injection IV & Certazone 250mg Injection IM for submission of reply to the above cited shortcomings.

- M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan has been granted additional "Solution for inhalation section" vide letter no. F.1-17/2012-Lic (Vol-III) dated 25-10-2023

96.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection conducted on 16-08-2022
	Evidence of approval of manufacturing facility	• Firm has submitted copy of letter no. F.1-17/2012-Lic (Vol-III) dated 25-10-2023 issued by Secretary CLB wherein "Ear/Eye Drops-II (General) section (New) has been granted. • Firm has also submitted panel inspection report dated 07-06-2023 wherein grant of additional section of "Solution for inhalation section".
	Dy. No. and date of submission	Tracking ID: 5LG-J7M-GZYL dated 13-12-2023
	Details of fee submitted	Rs.75,000/- dated 05-12-2023
	The proposed proprietary name / brand name	**Glycohale 25mcg/ml Inhalation Solution**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1 ml plastic ampoule of Inhalation Solution contains Glycopyrrolate …… 25mcg
	Pharmaceutical form of applied drug	**Inhalation Solution**
	Pharmacotherapeutic Group of (API)	Glycopyrrolate is in a class of medications called anticholinergics, used to treat peptic ulcer.
	Reference to Finished product specifications	As per Innovator's specs.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Registered drug by US FDA as LONHALA MAGNAIR (glycopyrrolate) inhalation solution, for oral inhalation use.
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	**MELODY HEALTHCARE PVT. LTD.** UNIT-1: PLOT NO. J-73, M.I.D.C Tarapur, Boisar, Dist., Palghar, 401506. Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of General information, General properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of drug substance.
	Stability studies	**Stability study conditions:** Real time: 30˚C ± 2˚C / 65% ± 5% RH for 18 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis, reference standard, Container closure and stabilities studies.
	Pharmaceutical equivalence	Pharmaceutical Equivalence have been established against the Lonhala Inahalation Solution of M/s Paripharma, USA.
	Analytical method validation/verification of product	Analytical Method Verification Studies of Drug substance and Analytical Method Validation Studies drug product have been submitted.

<table>
<tr><th colspan="4">STABILITY STUDY DATA</th></tr>
<tr><td colspan="2">Manufacturer of API</td><td colspan="2">MELODY HEALTHCARE PVT. LTD.
UNIT-1: PLOT NO. J-73, M.I.D.C Tarapur, Boisar, Dist., Palghar, 401506. Maharashtra, India.</td></tr>
<tr><td colspan="2">API Lot No.</td><td colspan="2">GLY/23002</td></tr>
<tr><td colspan="2">Description of Pack
(Container closure system)</td><td colspan="2">LDPE single-use containers</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="2">Accelerated: 40°C ± 2°C/NMT 25% RH
Real time: 30°C± 2°C/ 35% RH ± 5% RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="2">Real time: 6 months
Accelerated: 6 months</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="2">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>GIS-001</td><td>GIS-002</td></tr>
<tr><td colspan="2">Batch Size</td><td>5000 vials</td><td>5000 vials</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>07-2023</td><td>07-2023</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="2">02</td></tr>
<tr><td colspan="4">Administrative Portion</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="2">Firm has referred to onsite inspection report of this product:
XETINE 10mg Tablet, (Vortioxetine as Hydrobromide)
which was conducted on dated 06-07-2020 and was presented in 313th meeting of Registration Board held on 16-18 Nov, 2021.
Registration Board decided to approve registration of
XETINE 10mg Tablet, (Vortioxetine as Hydrobromide)

by M/s. Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small industrial Estate, Taxila, Pakistan. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
Following observations were reported in the report:
• The HPLC software is 21 CFR compliant.
• Audit trail on the testing reports of XETINE 10mg Tablet, is available.
• Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="2">Firm has submitted GMP certificate issued by Food & Drugs Administration, Maharashtra, valid till 14-04-2026.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="2">Copy of Clearance certificate attested by AD I&E DRAP, Lahore, issued inname of M/s Horizon Healthcare Lahore has been submitted.
<table>
<tr><th>Batch No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>GLY/23002</td><td>20.00 (Grams)</td><td>22-06-2023</td></tr>
</table>
• Firm has also submitted Loan letter from m/s Horizon Healthcare Lahore inname of m.s Horizon healthcare taxila.</td></tr>
</table>

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

Remarks of Evaluator [II]:

Section#	Observations	Firm's response
1.5.2	• Label claim for the dleievered dose shall be submitted.	Firm has submitted following detaile label claim: Each 1 mL contains Glycopyrrolate……25mcg *Each ml of deleivered dose contains 14.2mcg of Glycopyrrolate (equivalent to 11.4mcg Glycopyrronium).
1.5.9	• Referred innovator drug product is manufactured from blow-fill seal technology vials, whereas applied formulation is filled in LDPE ampoules. Justification shall be submitted for this difference.	Filling ampoule construction material of innovator drug product and applied drug product is same i.e., LDPE (Low Density Polyethylene)
3.2.P.1	• Details of the drug delivery device to be accompanied along with applied formulation shall be submitted.	We use Respironics device in which micro perforated membrane is used to aerosol the liq inhalation solution same technique is used in patent handset nebulizer device. Ref:109967

- For development of drug product before issuance of section approval letter, firm has submitted that development work was done in the said section after the panel inception wherein availability of manufacturing facility for applied formulation has been declared.

Decision: Approved

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

- M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan has been granted additional "Ear/Eye Drops-II (General) section vide letter no. F.1-17/2012-Lic (Vol-III) dated 25-10-2023

97.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection conducted on 16-08-2022
	Evidence of approval of manufacturing facility	• Firm has submitted copy of letter no. F.1-17/2012-Lic (Vol-III) dated 25-10-2023 issued by Secretary CLB wherein "Ear/Eye Drops-II (General) section (New) has been granted. • Firm has also submitted panel inspection report dated 07-06-2023 wherein grant of additional section of "Ear/Eye drop section (II) (general)(single dose).
	Dy. No. and date of submission	Tracking ID: 4NL-LXW-Q5G7 dated 29-01-2024
	Details of fee submitted	Rs.75,000/- dated 2023-11-22
	The proposed proprietary name / brand name	**Tafpro Ophthalmic Solution 0.0015% w/v**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	One single-dose container (0.3mL) of ophthalmic solution contains; Tafluprost……4.5 mcg
	Pharmaceutical form of applied drug	Ophthalmic Solution filled in LDPE single-use containers.
	Pharmacotherapeutic Group of (API)	Tafluprost is in a class of medications called prostaglandin analogs.
	Reference to Finished product specifications	As per Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZIOPTAN (Tafluprost ophthalmic solution) 0.0015% (w/v), Approved by US-FDA
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	**CENTURY PHARMACEUTIALS LTD.** Plant- 103, 104, 105, 106 GIDC Estate, HALOL-389350(INDIA).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of General information, General properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of drug substance.

	Stability studies	Stability study conditions: Real time: -20ºC ± 5ºC for 36 months Accelerated: 5 ºC ± 3ºC for 6 months
	Module-III (Drug Product):	The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis, reference standard, Container closure and stabilities studies.
	Pharmaceutical equivalence	Pharmaceutical Equivalence have been established against the Saflutan Ophthalmic Solution 0.0015% (w/v) of M/s Laboratoire Unither, France.
	Analytical method validation/verification of product	Analytical Method Verification Studies of Drug substance and Analytical Method Validation Studies drug product have been submitted.

STABILITY STUDY DATA

Manufacturer of API	**CENTURY PHARMACEUTIALS LTD.** Plant- 103, 104, 105, 106 GIDC Estate, HALOL-389350(INDIA).	
API Lot No.	09940002-TFP	
Description of Pack (Container closure system)	LDPE single-use containers packed in a pouch.	
Stability Storage Condition	Accelerated: 25°C ± 2°C / 60% RH ± 5% RH Real time: 5 ± 3°C	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	TFP- 001	TFP- 002
Batch Size	10,000	10,000
Manufacturing Date	08-2023	08-2023
No. of Batches	02	

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of this product: XETINE 10mg Tablet, (Vortioxetine as Hydrobromide) which was conducted on dated 06-07-2020 and was presented in 313th meeting of Registration Board held on 16-18 Nov, 2021. Registration Board decided to approve registration of XETINE 10mg Tablet, (Vortioxetine as Hydrobromide) by M/s. Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small industrial Estate, Taxila, Pakistan. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following observations were reported in the report: • The HPLC software is 21 CFR compliant.

		• Audit trail on the testing reports of XETINE 10mg Tablet, is available. • Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate no. S-GMP & GLP/22033183 issued by Food & Drugs Control Administration, India, valid till 10-03-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Clearance certificate attested by AD I&E DRAP, Islamabad, has been submitted.

Batch No.	Invoice No.,	Quantity Imported	Date of approval by DRAP
09940002-TFP	CPLEXP/T/23/ 1905	2.0000 (Grams)	26-Jul-2023

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

Remarks of Evaluator [II]:

Section#	Observations	Firm's response
3.2. S.4	• Justification shall be submitted for not including test of Microbial contents in drug substance specifications as recommended by the literature of innovator drug product.	We have followed the specifications and analyica lprocedure provided by thedug substance manufacturer.
2.3.R.1.1	• Minimum handling capacity of the mixing tank used for the manufacturing of trial batches shall be submitted.	Minimum handling capacity of the mixing tank is 5litres.

- For development of drug product before issuance of section approval letter, firm has submitted that development work was done in the said section after the panel inception wherein availability of manufacturing facility for applied formulation has been declared.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

98.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection conducted on 16-08-2022
	Evidence of approval of manufacturing facility	• Firm has submitted copy of letter no. F.1-17/2012-Lic (Vol-III) dated 25-10-2023 issued by Secretary CLB wherein "Ear/Eye Drops-II (General) section (New) has been granted. • Firm has also submitted panel inspection report dated 07-06-2023 wherein grant of additional section of "Ear/Eye drop section (II) (general)(single dose).
	Dy. No. and date of submission	Tracking ID: B4L-QWV-SX9U dated 29-01-2024
	Details of fee submitted	Rs.75,000/- dated 2023-11-14
	The proposed proprietary name / brand name	**Lifgra Ophthalmic Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	One single-dose container (0.2mL) of ophthalmic solution contains: Lifitegrast …… 0mg (5% w/v)
	Pharmaceutical form of applied drug	Ophthalmic Solution filled in LDPE single-use containers.
	Pharmacotherapeutic Group of (API)	Lifitegrast is in a class of medications called lymphocyte function-associated antigen-1 (LFA-1) antagonist.
	Reference to Finished product specifications	As per Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by **US-FDA**-XIIDRA (Lifitegrast ophthalmic solution) 5% (w/v), for topical ophthalmic use.
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	**Fuxin Long Rui Pharmaceutical CO., Ltd.** Address: Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxin City, Liaoning Province-123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of General information, General properties, Manufacturers, description of manufacturing process

		and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5% RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis, Characterization of impurities, reference standard or impurities, Container closure and stabilities studies.
	Pharmaceutical equivalence	Pharmaceutical Equivalence have been established against the XIIDRA 5% Ophthalmic Solution approved of Novartis Pharma
	Analytical method validation/verification of product	Analytical Method Verification Studies of Drug substance and Analytical Method Validation Studies drug product have been submitted.

STABILITY STUDY DATA		
Manufacturer of API	**Fuxin Long Rui Pharmaceutical CO., Ltd.** Address: Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxin City, Liaoning Province-123000, China	
API Lot No.	CHR007-20230118-D01-M04-01	
Description of Pack (Container closure system)	LDPE single-use containers packed in a pouch.	
Stability Storage Condition	Real time: 30°C ± 2°C/35% RH ± 5% Accelerated: 40°C ± 2°C/NMT 25% RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6(Months)	
Batch No.	LFT-001	LFT-002
Batch Size	10,000	10,000
Manufacturing Date	07-2023	07-2023
Date of Initiation	31-07-2023	31-07-2023
No. of Batches	02	

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of this product: XETINE 10mg Tablet, (Vortioxetine as Hydrobromide) which was conducted on dated 06-07-2020 and was presented in 313th meeting of Registration Board held on 16-18 Nov, 2021. Registration Board decided to approve registration of XETINE 10mg Tablet, (Vortioxetine as Hydrobromide)

<table>
<tr><td></td><td></td><td>by M/s. Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small industrial Estate, Taxila, Pakistan. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
Following observations were reported in the report:
• The HPLC software is 21 CFR compliant.
• Audit trail on the testing reports of XETINE 10mg Tablet, is available.
• Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm had provided DML no. LIAO 20150233 valid upto: 17-01-2027 issued by Liaoning Medical Products Administration</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of Clearance certificate attested by AD I&E DRAP, Islamabad, has been submitted.
<table>
<tr><th>Batch No.</th><th>Invoice No.,</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>CHR007-20230118-D01-M04-01</td><td>HOR4205240</td><td>0.50 (Kilograms)</td><td>20-Jul-2023</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. have been submitted.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing have been submitted.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.</td></tr>
</table>

Remarks of Evaluator [II]:

Section#	Observations	Firm's response
3.2.P.8.3	• Submit stability studies data for the 6th month time point. • Justification shall be submitted for not performing test of "sodium thiosulfate assay" during stability studies.	• Submitted • Firm has submitted 6th month time point stability data including performance of test of "sodium thiosulfate assay"

- For development of drug product before issuance of section approval letter, firm has submitted that development work was done in the said section after the panel inception wherein availability of manufacturing facility for applied formulation has been declared.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case no. 04 Registration applications considered on priority as per decision of Authority due to market shortage.

99.	**Name, address of Applicant / Importer**	**M/s Lab Diagnostic Systems (SMC) Pvt. Ltd.**
	Details of Drug Sale License of importer	**License No:** 01-374-0006-96845D **Address:** 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan **Validity:** 11-01-2022 **Status:** License to sell drugs as a Distributor Firm has also submitted receipt of application of renewal of DSL applied to Directorate of Drugs Control Punjab (Reference no. 374-19674461-2022)
	Name and address of marketing authorization holder (abroad)	M/s Shanghai Hengrui Pharmaceutical Co., Ltd. 279 Wenjing Road, Minhang District, Shanghai 200245, China
	Name, address of manufacturer(s)	M/s Shanghai Hengrui Pharmaceutical Co., Ltd. 279 Wenjing Road, Minhang District, Shanghai 200245, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted CoPP certificate (No. 79XW-EXPE) valid till 09-11-2025 issued by US FDA for Sevoflurane Inhalant 250ml. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. The name of importing country on CoPP is mentioned as Pakistan. Submitted COPP is online verifiable from FDA "Online Portal for Verification of eCPPs for Human Drug Products" vide following web link: FECV - FURLS Export Certificate Validator (fda.gov)
	Details of letter of authorization / sole agency agreement	Not submitted
	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
	Tracking ID and date of submission	Trackin ID no. MAQ-E65-QA8W dated 19-02-2024
	Details of fee submitted	PKR 150000/- 20-07-2022

	The proposed proprietary name / brand name	**VISEVO (SEVOFLURANE USP INHALATION ANESTHETIC - 250 ml)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sevoflurane …. 250ml (1ml/ml)
	Pharmaceutical form of applied drug	Liquid for inhalation
	Pharmacotherapeutic Group of (API)	Inhalation Anaesthesia
	Reference to Finished product specifications	USP
	Proposed Pack size	1's: 250ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved.
	For generic drugs (me-too status)	Sevof liquid for inhalation 250ml of M/s Getz (Reg.# 103781)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Jiangsu Hengrui Pharmaceuticals Co., Ltd. 22 Jinqiao Road, Dapu Industrial Park, Economic and Technological Development Zone, Lianyungang, Jiangsu 222069, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has comparative studies against Sevoflurane liquid 250ml of M/s Maruishi Pharmaceutical Company Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type III amber glass bottle

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 75% ± 5% The real time stability study data for 3 batches is for 24 months only.
Evaluation by PEC: • Firm has submitted notarized letter of Authorisation shall be submitted in name of M/s Lab Diagnostic Systems (SMC) Pvt. Ltd from market authorisation holder i.e., M/s Shanghai Hengrui Pharmaceutical Co., Ltd. for the instant product.		
Decision: Approved as per policy of inspection of manufacturer abroad.		

Agenda of Evaluator PEC-III

Case No. 01 Registration applications of cases of New Section / New License

M/s Nagarsons Pharmaceuticals (Pvt) Ltd. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad

100.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals (Pvt) Ltd. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Nagarsons Pharmaceuticals (Pvt) Ltd. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license dated 7th June 2021 for following sections: 1. Tablet (General) 2. Capsule (General) 3. Cream /ointment/Lotion/Gel
	Evidence of approval of manufacturing facility	Firm has been granted new license dated 7th June 2021 for following sections: 1. Tablet (General) 2. Capsule (General) 3. Cream /ointment/Lotion/Gel
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. EM7-UVS-R56T: 25-03-2024
	Details of fee submitted	PKR 30,000/-: 19-03-2024
	The proposed proprietary name / brand name	**TAMSONAG 0.4mg Capsule**
	Strength / concentration of drug of Active	Each Capsule Contains:

	Pharmaceutical ingredient (API) per unit	Tamsulosin HCl (as SR Pellets).…0.4mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Alpha blocker
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Maxflow Capsule by CCL
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the innovator's i.e. Flowmax Capsule of CCL. Firm has submitted CDP studies in 3 medium against the innovator's i.e. Flowmax Capsule of CCL.

	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.		
API Lot No.	TMS415		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 Capsule	1000 Capsule	1000 Capsule
Manufacturing Date	07-2023	07-2023	07-2023
Date of Initiation	11-07-2023	12-07-2023	13-07-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate on the basis of evaluation conducted on 14-06-2022 and valid for 02 years
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 2Kg tamsulosin pellets dated 10-06-2023.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s Getz Pharma Pvt Ltd. Plot No.1, Sector 25, Korangi Industrial Area, Karachi

101.	Name, address of Applicant / Marketing Authorization Holder	**M/s Getz Pharma Pvt Ltd. Plot No.1, Sector 25, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Getz Pharma Pvt Ltd. Plot No.1, Sector 25, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-11-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 27-02-2023 specifying Dry Powder Vial Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24506 dated 06-10-2023
	Details of fee submitted	PKR 30,000/- Dated 27-01-2022
	The proposed proprietary name / brand name	**2GET IV/IM 500mg Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoperazone Sodium Eq. to Cefoperazone…250mg Sulbactam Sodium Eq. to Sulbactam…250mg
	Pharmaceutical form of applied drug	Sterile white to almost white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	1's
	Proposed unit price	300
	The status in reference regulatory authorities	(PMDA Japan Approved)
	For generic drugs (me-too status)	2Sum injection by Sami
	Name and address of API manufacturer.	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co Ltd West Side of Yanbin Road Economic Development Zone Feixian China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form,

		manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against 2sum injection of Healthtek
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA

Manufacturer of API	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co Ltd West Side of Yanbin Road Economic Development Zone Feixian China		
API Lot No.	11C0312207001		
Description of Pack (Container closure system)	Glass Vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C020DS01	C020DS02	
Batch Size	2000 vials	2000 vials	
Manufacturing Date	09-2022	09-2022	
Date of Initiation	17-10-2022	17-10-2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML of the firm issued by CFDA China valid till 26-10-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of License to Import specifying import of 20Kg Cefoperazone sodium-Sulbactam sodium dated 18-08-2022. Firm has also

		submitted copy of Goods Declaration dated 10-08-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

- Firm has got approval of new section on 27-02-2023 while the stability batches have been manufactured on September 2022.

Sr. No	Shortcomings communicated	Response by the firm
1.	The approval of the requisite manufacturing facility i.e. Dry Powder Vial Injection (Cephalosporin) section was granted by Licensing Division DRAP on 27-02-2023, and the inspection by the panel was carried out on 16-11-2022. You have manufactured the batches in September 2022, before the grant of section as well as before the inspection by panel. Clarification is required how manufacturing of the trial batches of a sterile product is carried out before formal approval / inspection of the said facility.	This is to bring to your kind information that we are using ready to fill cefoperazone sodium and sulbactam sodium for filling in vials and no excipient is used in the formulation of said product. The filling of bulk API has been performed in our R&D section under under Laminar Flow Hood with HEPA filter in aseptic conditions.
2.	Licensing Division DRAP has approved the facility of Product development laboratory (Cephalosporin) on 27-02-2023, clarification is required whether the product development laboratory is equipped by facility for development and manufacturing of sterile products.	

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

102.	Name, address of Applicant / Marketing Authorization Holder	**M/s Getz Pharma Pvt Ltd. Plot No.1, Sector 25, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Getz Pharma Pvt Ltd. Plot No.1, Sector 25, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-11-2023.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 27-02-2023 specifying Dry Powder Vial Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24507 dated 06-10-2023
	Details of fee submitted	PKR 30,000/- Dated 27-01-2022
	The proposed proprietary name / brand name	**2GET IV/IM 1g Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoperazone Sodium Eq. to Cefoperazone…500mg Sulbactam Sodium Eq. to Sulbactam…500mg
	Pharmaceutical form of applied drug	Sterile white to almost white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	1's
	Proposed unit price	600
	The status in reference regulatory authorities	(PMDA Japan Approved)
	For generic drugs (me-too status)	2Sum injection by Sami
	Name and address of API manufacturer.	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co Ltd West Side of Yanbin Road Economic Development Zone Feixian China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process

		and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against 2sum injection of Healthtek
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA

Manufacturer of API	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co Ltd West Side of Yanbin Road Economic Development Zone Feixian China		
API Lot No.	11C0312207001		
Description of Pack (Container closure system)	Glass Vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C021DS01	C021DS02	
Batch Size	2000 vials	2000 vials	
Manufacturing Date	09-2022	09-2022	
Date of Initiation	17-10-2022	17-10-2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML of the firm issued by CFDA China valid till 26-10-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of License to Import specifying import of 20Kg Cefoperazone sodium-Sulbactam sodium dated 18-08-2022. Firm has also submitted copy of Goods Declaration dated 10-08-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

- Firm has got approval of new section on 27-02-2023 while the stability batches have been manufactured on September 2022.

Sr. No	Shortcomings communicated	Response by the firm
1.	The approval of the requisite manufacturing facility i.e. Dry Powder Vial Injection (Cephalosporin) section was granted by Licensing Division DRAP on 27-02-2023, and the inspection by the panel was carried out on 16-11-2022. You have manufactured the batches in September 2022, before the grant of section as well as before the inspection by panel. Clarification is required how manufacturing of the trial batches of a sterile product is carried out before formal approval / inspection of the said facility.	This is to bring to your kind information that we are using ready to fill cefoperazone sodium and sulbactam sodium for filling in vials and no excipient is used in the formulation of said product. The filling of bulk API has been performed in our R&D section under under Laminar Flow Hood with HEPA filter in aseptic conditions.
2.	Licensing Division DRAP has approved the facility of Product development laboratory (Cephalosporin) on 27-02-2023, clarification is required whether the product development laboratory is equipped by facility for development and manufacturing of sterile products.	

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

103.	Name, address of Applicant / Marketing Authorization Holder	**M/s Getz Pharma Pvt Ltd. Plot No.1, Sector 25, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Getz Pharma Pvt Ltd. Plot No.1, Sector 25, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-11-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 27-02-2023 specifying Dry Powder Vial Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24885 dated 12-10-2023
	Details of fee submitted	PKR 30,000/- Dated 27-01-2022

	The proposed proprietary name / brand name	**2GET IV/IM 2g Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoperazone Sodium Eq. to Cefoperazone…1g Sulbactam Sodium Eq. to Sulbactam…1g
	Pharmaceutical form of applied drug	Sterile white to almost white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	1's
	Proposed unit price	800
	The status in reference regulatory authorities	Approved in 03 European countries, i.e., **Bulgaria:** Sulcef 1g/1g powder for solution for injection **Lithuania:** Sulcef 1g/1g powder for solution for injection **Slovakia:** Sulcef 2g powder for solution for injection
	For generic drugs (me-too status)	2Sum injection by Sami
	Name and address of API manufacturer.	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co Ltd West Side of Yanbin Road Economic Development Zone Feixian China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative	Firm has submitted results of pharmaceutical

	Dissolution Profile	equivalence for their product against 2sum injection of Healthtek
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA			
Manufacturer of API	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co Ltd West Side of Yanbin Road Economic Development Zone Feixian China		
API Lot No.	11C0312207001		
Description of Pack (Container closure system)	Glass Vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C022DS01	C022DS02	
Batch Size	2000 vials	2000 vials	
Manufacturing Date	09-2022	09-2022	
Date of Initiation	17-10-2022	17-10-2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML of the firm issued by CFDA China valid till 26-10-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of License to Import specifying import of 20Kg Cefoperazone sodium-Sulbactam sodium dated 18-08-2022. Firm has also submitted copy of Goods Declaration dated 10-08-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

- Firm has got approval of new section on 27-02-2023 while the stability batches have been manufactured on September 2022.

Sr. No	Shortcomings communicated	Response by the firm
1.	The approval of the requisite manufacturing facility i.e. Dry Powder Vial Injection	This is to bring to your kind information that we are using ready to fill cefoperazone sodium and

	(Cephalosporin) section was granted by Licensing Division DRAP on 27-02-2023, and the inspection by the panel was carried out on 16-11-2022. You have manufactured the batches in September 2022, before the grant of section as well as before the inspection by panel. Clarification is required how manufacturing of the trial batches of a sterile product is carried out before formal approval / inspection of the said facility.	sulbactam sodium for filling in vials and no excipient is used in the formulation of said product. The filling of bulk API has been performed in our R&D section under under Laminar Flow Hood with HEPA filter in aseptic conditions.
2.	Licensing Division DRAP has approved the facility of Product development laboratory (Cephalosporin) on 27-02-2023, clarification is required whether the product development laboratory is equipped by facility for development and manufacturing of sterile products.	

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.

M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi was granted Drug Manufacturing License (DML No. 000947) dated 11-11-2021 for following sections:
1. Liquid Injectable Infusion (SVP) LDPE (General)
2. Liquid Injectable Infusion (LVP) LDPE (General)

The detail of the previously considered and currently applied applications applied by the firm is submitted below:

Sr. No	Section	No of molecules	No of products
1.	Liquid Injectable Infusion (SVP) LDPE (General)	2	4
2.	Liquid Injectable Infusion (LVP) LDPE (General)	6	16

104.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5XZ-862-TLE8: 21-02-2024
	Details of fee submitted	PKR 30,000/- : 12-01-2024
	The proposed proprietary name / brand name	**JECTSOL RLD Infusion 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Sodium chloride…….0.6g Calcium Chloride dihydrate…..0.02g Potassium Chloride……..0.03g Sodium lactate……..0.31g Dextrose anydrous……5g
	Pharmaceutical form of applied drug	IV Infusion
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	USP
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved. 5% Dextrose in Lactated Ringer's Injection by B. Braun
	For generic drugs (me-too status)	Ringolact-D injection by Otsuka Pakistan
	Name and address of API manufacturer.	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** CFL CLFCHEMISCHE FABRIK LEHRTE GMBH & CO.KG KÖTHENWALDSTR. 2-6 - 31275 LEHRTE GERMANY **Sodium lactate** Wuhan Sanjing Space Good Biotech Co Ltd Hebei Province China **Dextrose:** Weifang Shengtai Medicine Co., Ltd. The east of Changda Road, Changle County, Weifang city, Shandong province, P.R.China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities,

		specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data for all drug substances
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product 'Sterifluid-RLD Infusion by M/s FDL Pharma."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** CFL CLFCHEMISCHE FABRIK LEHRTE GMBH & CO.KG KÖTHENWALDSTR. 2- 6 - 31275 LEHRTE GERMANY **Sodium lactate** Wuhan Sanjing Space Good Biotech Co Ltd Hebei Province China **Dextrose:** Weifang Shengtai Medicine Co., Ltd. The east of Changda Road, Changle County, Weifang city, Shandong province, P.R.China
API Lot No.	**Sodium Chloride:** 220903 **Calcium chloride:** 221225 **Potassium chloride:** 3422000506 **Sodium lactate:** 22RS12234 **Dextrose:** XW20220913
Description of Pack (Container closure system)	Polypropylene
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 1	Trial # 2	Trial # 3
Batch Size	100 Bottles	100 Bottles	100 Bottles
Manufacturing Date	04-2023	04-2023	04-2023
Date of Initiation	10-04-2023	11-04-2023	12-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** Firm has submitted copy of Manufacturing License (No Hebei 20150116) issued by NMPA China valid till 11-08-2025. **Calcium chloride:** Firm has submitted copy of Manufacturing License (No Hebei 20150116) issued by NMPA China valid till 11-08-2025. **Potassium chloride:** Firm has submitted copy of Eudra GMP certificate issued based on the inspection dated 28-04-2021. **Sodium lactate:** **Dextrose:**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium Chloride:** Firm has submitted copy of clearance certificate dated 02-11-2022. The invoice declare purchase of 25000Kg sodium chloride. **Calcium chloride:** Firm has submitted copy of clearance certificate dated 02-03-2023. The invoice declare purchase of 1000Kg calcium chloride. **Potassium chloride:** Firm has submitted copy of clearance certificate dated 17-11-2022. The invoice declare purchase of 1000Kg potassium chloride. **Sodium lactate:** Firm has submitted copy of clearance certificate dated 02-03-2023. The invoice declare purchase of 7500Kg Sodium lactate. **Dextrose:** Firm has submitted copy of clearance certificate dated 31-10-2022. The invoice declare purchase of 24000Kg dextrose anhydrous.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm

1.	Submit Module 3.2.S of sodium lactate from the API manufacturer since all details are submitted of Lyoyang Longmen Pharma instead of the API manufacturer.	Submitted by the firm
2.	Submit valid GMP certificate of each drug substance manufacturer.	Submitted by the firm
3.	Submit water loss studies conducted during stability since your container closure system is semi-permeable.	Submitted by the firm

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

105.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. BZQ-VPS-8Y2M: 21-02-2024
	Details of fee submitted	PKR 30,000/- : 12-01-2024
	The proposed proprietary name / brand name	**JECTSOL RLD Infusion 1000ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Sodium chloride…….0.6g Calcium Chloride dihydrate…..0.02g Potassium Chloride……..0.03g Sodium lactate……..0.31g Dextrose anydrous……5g
	Pharmaceutical form of applied drug	IV Infusion
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	USP

	Proposed Pack size	1000ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved. 5% Dextrose in Lactated Ringer's Injection by B. Braun
	For generic drugs (me-too status)	Ringolact-D injection by Otsuka Pakistan
	Name and address of API manufacturer.	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** CFL CLFCHEMISCHE FABRIK LEHRTE GMBH & CO.KG KÖTHENWALDSTR. 2-6 - 31275 LEHRTE GERMANY **Sodium lactate** Wuhan Sanjing Space Good Biotech Co Ltd Hebei Province China **Dextrose:** Weifang Shengtai Medicine Co., Ltd. The east of Changda Road, Changle County, Weifang city, Shandong province, P.R.China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data for all drug substances
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative	Firm has submitted results of pharmaceutical

	Dissolution Profile	equivalence for the quality tests for their product against the comparator product 'Sterifluid-RLD Infusion by M/s FDL Pharma."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** CFL CLFCHEMISCHE FABRIK LEHRTE GMBH & CO.KG KÖTHENWALDSTR. 2- 6 - 31275 LEHRTE GERMANY **Sodium lactate** Wuhan Sanjing Space Good Biotech Co Ltd Hebei Province China **Dextrose:** Weifang Shengtai Medicine Co., Ltd. The east of Changda Road, Changle County, Weifang city, Shandong province, P.R.China		
API Lot No.	**Sodium Chloride:** 220903 **Calcium chloride:** 221225 **Potassium chloride:** 3422000506 **Sodium lactate:** 22RS12234 **Dextrose:** XW20220913		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 4	Trial # 5	Trial # 6
Batch Size	100 Bottles	100 Bottles	100 Bottles
Manufacturing Date	04-2023	04-2023	04-2023
Date of Initiation	10-04-2023	11-04-2023	12-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** Firm has submitted copy of Manufacturing License (No Hebei 20150116) issued by NMPA China valid till 11-08-2025. **Calcium chloride:** Firm has submitted copy of Manufacturing License (No Hebei 20150116) issued by NMPA China valid till 11-08-2025. **Potassium chloride:** Firm has submitted copy of Eudra GMP certificate issued based on the inspection dated 28-04-2021. **Sodium lactate:**

		Dextrose:
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium Chloride:** Firm has submitted copy of clearance certificate dated 02-11-2022. The invoice declare purchase of 25000Kg sodium chloride. **Calcium chloride:** Firm has submitted copy of clearance certificate dated 02-03-2023. The invoice declare purchase of 1000Kg calcium chloride. **Potassium chloride:** Firm has submitted copy of clearance certificate dated 17-11-2022. The invoice declare purchase of 1000Kg potassium chloride. **Sodium lactate:** Firm has submitted copy of clearance certificate dated 02-03-2023. The invoice declare purchase of 7500Kg Sodium lactate. **Dextrose:** Firm has submitted copy of clearance certificate dated 31-10-2022. The invoice declare purchase of 24000Kg dextrose anhydrous.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit Module 3.2.S of sodium lactate from the API manufacturer since all details are submitted of Lyoyang Longmen Pharma instead of the API manufacturer.	Submitted by the firm
2.	Submit valid GMP certificate of each drug substance manufacturer.	Submitted by the firm
3.	Submit water loss studies conducted during stability since your container closure system is semi-permeable.	Submitted by the firm

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

106.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. SDN-5RQ-SRQA: 27-03-2024
	Details of fee submitted	PKR 30,000/- : 12-01-2024
	The proposed proprietary name / brand name	**JECTSOL- 25% Infusion 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Dextrose anhydrous……25g
	Pharmaceutical form of applied drug	IV Infusion
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	BP
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Glucose 25% Intravenous Infusion TGA Approved
	For generic drugs (me-too status)	Macsol 25% Infusion of Searle
	Name and address of API manufacturer.	Weifang Shengtai Medicine Co., Ltd The east of Changda Road, Changle County, Weifang city, Shandong province, P.R.China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data for drug substances
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical

		development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product '"Macsol Infusion manufactured by Searle Pakistan Ltd."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Weifang Shengtai Medicine Co., Ltd The east of Changda Road, Changle County, Weifang city, Shandong province, P.R.China.		
API Lot No.	XW20220913		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T010	T011	T012
Batch Size	100 Bottles	100 Bottles	100 Bottles
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	10-01-2023	11-01-2023	12-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Manufacturing license (No. Lu20200513) issued by NMPA China valid till 16-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 31-10-2022. The invoice declare purchase of 24000Kg Dextrose anhydrous.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit water loss studies conducted during stability since your container closure system is semi-permeable.	Submitted by the firm

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

107.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. TVB-YRU-H83E: 27-03-2024
	Details of fee submitted	PKR 30,000/- : 12-01-2024
	The proposed proprietary name / brand name	**JECTSOL DS 1/2 Infusion 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Sodium chloride…….0.45g Dextrose anydrous……5g
	Pharmaceutical form of applied drug	IV Infusion
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	USP
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved. 5% Dextrose 0.45% Sodium chloride Injection
	For generic drugs (me-too status)	PLADEXSAL ½ INFUSION by Otsuka

	Name and address of API manufacturer.	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Dextrose:** Weifang Shengtai Medicine Co., Ltd The east of Changda Road, Changle County, Weifang city, Shandong province, P.R.China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data for all drug substances
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product '"Macsol DS ½ Infusion manufactured by Searle Pakistan Ltd."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Dextrose:** Weifang Shengtai Medicine Co., Ltd The east of Changda Road, Changle County, Weifang city, Shandong province, P.R.China.
API Lot No.	**Sodium Chloride:** 220903 **Dextrose:** XW20220913
Description of Pack (Container closure system)	Polypropylene
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 1	Trial # 2	Trial # 3
Batch Size	100 Bottles	100 Bottles	100 Bottles
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	14-01-2023	15-01-2023	16-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** Firm has submitted copy of Manufacturing License (No Hebei 20150116) issued by NMPA China valid till 11-08-2025. **Dextrose:** Firm has submitted copy of Manufacturing license (No. Lu20200513) issued by NMPA China valid till 16-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium Chloride:** Firm has submitted copy of clearance certificate dated 02-11-2022. The invoice declare purchase of 25000Kg sodium chloride. **Dextrose:** Firm has submitted copy of clearance certificate dated 31-10-2022. The invoice declare purchase of 24000Kg Dextrose anhydrous.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit water loss studies conducted during stability since your container closure system is semi-permeable.	Submitted by the firm

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

108.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai

		District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. 33U-JMN-AG2Z: 27-03-2024
	Details of fee submitted	PKR 30,000/- : 12-01-2024
	The proposed proprietary name / brand name	**JECTSOL DS 1/2 Infusion 1000ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Sodium chloride…….0.45g Dextrose anydrous……5g
	Pharmaceutical form of applied drug	IV Infusion
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	USP
	Proposed Pack size	1000ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved. 5% Dextrose 0.45% Sodium chloride Injection
	For generic drugs (me-too status)	PLADEXSAL ½ INFUSION by Otsuka
	Name and address of API manufacturer.	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Dextrose:** Weifang Shengtai Medicine Co., Ltd The east of Changda Road, Changle County, Weifang city, Shandong province, P.R.China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general

		properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data for all drug substances
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product '"Macsol DS ½ Infusion manufactured by Searle Pakistan Ltd."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Dextrose:** Weifang Shengtai Medicine Co., Ltd The east of Changda Road, Changle County, Weifang city, Shandong province, P.R.China.		
API Lot No.	**Sodium Chloride:** 220903 **Dextrose:** XW20220913		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 4	Trial # 5	Trial # 6
Batch Size	100 Bottles	100 Bottles	100 Bottles
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	14-01-2023	15-01-2023	16-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** Firm has submitted copy of Manufacturing License (No Hebei 20150116) issued by NMPA China valid till 11-08-2025. **Dextrose:** Firm has submitted copy of Manufacturing license (No. Lu20200513) issued by NMPA China valid till 16-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium Chloride:** Firm has submitted copy of clearance certificate dated 02-11-2022. The invoice declare purchase of 25000Kg sodium chloride. **Dextrose:** Firm has submitted copy of clearance certificate dated 31-10-2022. The invoice declare purchase of 24000Kg Dextrose anhydrous.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit water loss studies conducted during stability since your container closure system is semi-permeable.	Submitted by the firm

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

109.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. 52W-5H4-1L3R: 27-03-2024
	Details of fee submitted	PKR 30,000/- : 17-01-2024
	The proposed proprietary name / brand name	**JECTSOL-R Infusion 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Sodium chloride…….0.86g Calcium Chloride dihydrate…..0.033g Potassium Chloride……..0.03g
	Pharmaceutical form of applied drug	IV Infusion
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	USP
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved. Ringer's Solution for Infusion
	For generic drugs (me-too status)	MACRIN RS I.V INFUSION by Searle
	Name and address of API manufacturer.	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** CFL CLFCHEMISCHE FABRIK LEHRTE GMBH & CO.KG KÖTHENWALDSTR. 2-6 - 31275 LEHRTE GERMANY
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data for all drug substances
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical

		development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product '"Macrin RS Infusion manufactured by Searle Pakistan Ltd."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** CFL CLFCHEMISCHE FABRIK LEHRTE GMBH & CO.KG KÖTHENWALDSTR. 2- 6 - 31275 LEHRTE GERMANY		
API Lot No.	**Sodium Chloride:** 220903 **Calcium chloride:** 221225 **Potassium chloride:** 3422000506		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T016	T017	T018
Batch Size	100 Bottles	100 Bottles	100 Bottles
Manufacturing Date	04-2023	04-2023	04-2023
Date of Initiation	10-04-2023	11-04-2023	12-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** Firm has submitted copy of Manufacturing License (No Hebei 20150116) issued by NMPA China valid till 11-08-2025. **Calcium chloride:** Firm has submitted copy of Manufacturing License (No Hebei 20150116) issued by NMPA China valid till 11-08-2025.

		Potassium chloride: Firm has submitted copy of Eudra GMP certificate issued based on the inspection dated 28-04-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium Chloride:** Firm has submitted copy of clearance certificate dated 02-11-2022. The invoice declare purchase of 25000Kg sodium chloride. **Calcium chloride:** Firm has submitted copy of clearance certificate dated 02-03-2023. The invoice declare purchase of 1000Kg calcium chloride. **Potassium chloride:** Firm has submitted copy of clearance certificate dated 17-11-2022. The invoice declare purchase of 1000Kg potassium chloride.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit water loss studies conducted during stability since your container closure system is semi-permeable.	Submitted by the firm

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s Gray's Pharmaceuticals, Plot No 2, Street No. N-3, National Industrial Zone Rawat

110.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Gray's Pharmaceuticals, Plot No 2, Street No. N-3, National Industrial Zone Rawat.**
	Name, address of Manufacturing site.	M/s Gray's Pharmaceuticals, Plot No 2, Street No. N-3, National Industrial Zone Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated issued on the basis of inspection dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated issued on the basis of inspection dated 14-09-2021 which specifies Sachet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5099: 22-02-2023
	Details of fee submitted	PKR 30,000/-: 18-01-2023
	The proposed proprietary name / brand name	**ACELATOR Sachet 200mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains: Acetylcysteine……200mg
	Pharmaceutical form of applied drug	Sachet
	Pharmacotherapeutic Group of (API)	Mucolytic agent
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(MHRA** Approved)
	For generic drugs (me-too status)	Mucolator Sachet by Abbott
	Name and address of API manufacturer.	Wuhan Grand Hoyo Co Ltd. No 1, Industrial Park Gedian Economy Development Zone, E' Zhou City, Hubei China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Mucolator Sachet of Abbott

		Firm has submitted results of CDP for their product against Mucolator Sachet of Abbott
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Wuhan Grand Hoyo Co Ltd. No 1, Industrial Park Gedian Economy Development Zone, E' Zhou City, Hubei China		
API Lot No.	S202202004		
Description of Pack (Container closure system)	Aluminium foil Sachet		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 Sachet	500 Sachet	500 Sachet
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	12-09-2022	12-09-2022	12-09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No, HB20190479) issued by CFDA China valid till 03-03-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 08-03-2022 specifying 0.6Kg Acetylcysteine. Firm has also submitted copy of DHL invoice
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of stability batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted compliance certificate of HPLc system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s Don Valley Pharmaceuticals (Pvt) Ltd 31-Km, Ferozepur Road, Lahore.

111.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Don Valley Pharmaceuticals (Pvt) Ltd 31-Km, Ferozepur Road, Lahore.**
	Name, address of Manufacturing site.	M/s Don Valley Pharmaceuticals (Pvt) Ltd 31-Km, Ferozepur Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 15-08-2022 issued on the basis of inspection dated 11-08-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 15-08-2022 issued on the basis of inspection dated 11-08-2022 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27151: 17-11-2023
	Details of fee submitted	PKR 30,000/-: 25-09-2023
	The proposed proprietary name / brand name	**EMPADON 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…10mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	In house specs
	Proposed Pack size	14’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Xenglu Tablet by Hilton
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County Fuxin City Liaoning Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general

		properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Empator Tablet of Martin Dow Firm has submitted results of CDP for their product against Empator Tablet of Martin Dow
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA

Manufacturer of API	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County Fuxin City Liaoning Province China.		
API Lot No.	L-E-20211130-D06-E06-02		
Description of Pack (Container closure system)	Alu-alu blister pack		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IX-22-001	IX-22-002	IX-22-003
Batch Size	700 Tablet	700 Tablet	700 Tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	26-05-2022	27-05-2022	27-05-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML of the firm issued by CFDA China
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate specifying import of 0.25Kg Empagliflozin. The clearance certificate is issued on 20-04-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted compliance certificate of HPLC system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

112.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Don Valley Pharmaceuticals (Pvt) Ltd 31-Km, Ferozepur Road, Lahore.**
	Name, address of Manufacturing site.	M/s Don Valley Pharmaceuticals (Pvt) Ltd 31-Km, Ferozepur Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 15-08-2022 issued on the basis of inspection dated 11-08-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 15-08-2022 issued on the basis of inspection dated 11-08-2022 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27573: 24-11-2023
	Details of fee submitted	PKR 30,000/-: 27-10-2023
	The proposed proprietary name / brand name	**EMPADON Plus Tablet 12.5/1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…12.5mg Metformin HCl……1000mg

	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	In house specs
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Xenglu Tablet by Hilton
	Name and address of API manufacturer.	**Empagliflozin:** Zhejiang Hongyuan Pharmaceutical Co Ltd No 6 Donghai 4th Avenue Zhejiang Toumengang Economic Development Zone Linhai City Taizhou Zhejiang China **Metformin:** Aarti Drugs Limited Plot No 211-213 Road No 2, GIDC Sarigam Dist Valsad Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Metformin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Diampa Tablet of Getz Pharma Firm has submitted results of CDP for their product against Diampa Tablet of Getz Pharma

	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Empagliflozin:** Zhejiang Hongyuan Pharmaceutical Co Ltd No 6 Donghai 4th Avenue Zhejiang Toumengang Economic Development Zone Linhai City Taizhou Zhejiang China **Metformin:** Aarti Drugs Limited Plot No 211-213 Road No 2, GIDC Sarigam Dist Valsad Gujrat India		
API Lot No.	**Empagliflozin:** EPG220801 **Metformin:** MEF/11124163		
Description of Pack (Container closure system)	Alu-alu blister pack		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	KE-23-001	KE-23-002	KE-23-003
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	07-01-2023	08-01-2023	08-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of DML of the firm issued by CFDA China **Metformin:** Firm has submitted copy of GMP certificate issued by Food & Drugs Administration Gujrat State India valid till 20-06-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of clearance certificate specifying import of 1.5Kg Empagliflozin. The clearance certificate is issued on 07-10-2022. **Metformin:** Firm has submitted copy of commercial invoice for import of 1000kg metformin. The invoice is cleared by AD (I&E) dated 03-02-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted compliance certificate of HPLc system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC:		

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

113.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Don Valley Pharmaceuticals (Pvt) Ltd 31-Km, Ferozepur Road, Lahore.**
	Name, address of Manufacturing site.	M/s Don Valley Pharmaceuticals (Pvt) Ltd 31-Km, Ferozepur Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 15-08-2022 issued on the basis of inspection dated 11-08-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 15-08-2022 issued on the basis of inspection dated 11-08-2022 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. BBP-8VL-Z6H2: 13-03-2024
	Details of fee submitted	PKR 30,000/-: 27-10-2023
	The proposed proprietary name / brand name	**EMPADON Plus Tablet 5/500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…5mg Metformin HCl……500mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	In house specs
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Xenglu Tablet by Hilton
	Name and address of API manufacturer.	**Empagliflozin:** Zhejiang Hongyuan Pharmaceutical Co Ltd No 6 Donghai 4th Avenue Zhejiang Toumengang Economic Development Zone Linhai City Taizhou Zhejiang China **Metformin:** Aarti Drugs Limited Plot No 211-213 Road No 2, GIDC Sarigam Dist Valsad Gujrat India

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Metformin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Diampa M Tablet of Getz Pharma Firm has submitted results of CDP for their product against Diampa M Tablet of Getz Pharma
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Empagliflozin:** Zhejiang Hongyuan Pharmaceutical Co Ltd No 6 Donghai 4th Avenue Zhejiang Toumengang Economic Development Zone Linhai City Taizhou Zhejiang China **Metformin:** Aarti Drugs Limited Plot No 211-213 Road No 2, GIDC Sarigam Dist Valsad Gujrat India
API Lot No.	**Empagliflozin:** EPG220801 **Metformin:** MEF/11124163
Description of Pack (Container closure system)	Alu-alu blister pack
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	KE-23-001	KE-23-002	KE-23-003
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	14-01-2023	14-01-2023	14-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of DML of the firm issued by CFDA China **Metformin:** Firm has submitted copy of GMP certificate issued by Food & Drugs Administration Gujrat State India valid till 20-06-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of clearance certificate specifying import of 1.5Kg Empagliflozin. The clearance certificate is issued on 07-10-2022. **Metformin:** Firm has submitted copy of commercial invoice for import of 1000kg metformin. The invoice is cleared by AD (I&E) dated 03-02-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted compliance certificate of HPLc system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

114.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Don Valley Pharmaceuticals (Pvt) Ltd 31-Km, Ferozepur Road, Lahore.**
	Name, address of Manufacturing site.	M/s Don Valley Pharmaceuticals (Pvt) Ltd 31-Km, Ferozepur Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 15-08-2022 issued on the basis of inspection dated 11-08-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 15-08-2022 issued on the basis of inspection dated 11-08-2022 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. ZD4-WPE-XEA9: 13-03-2024
	Details of fee submitted	PKR 30,000/-: 27-10-2023
	The proposed proprietary name / brand name	**EMPADON Plus Tablet 5/1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…5mg Metformin HCl……1000mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	In house specs
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Xenglu Tablet by Hilton
	Name and address of API manufacturer.	**Empagliflozin:** Zhejiang Hongyuan Pharmaceutical Co Ltd No 6 Donghai 4th Avenue Zhejiang Toumengang Economic Development Zone Linhai City Taizhou Zhejiang China **Metformin:** Aarti Drugs Limited Plot No 211-213 Road No 2, GIDC Sarigam Dist Valsad Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Metformin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Diampa M Tablet of Getz Pharma Firm has submitted results of CDP for their product against Diampa M Tablet of Getz Pharma
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** Zhejiang Hongyuan Pharmaceutical Co Ltd No 6 Donghai 4th Avenue Zhejiang Toumengang Economic Development Zone Linhai City Taizhou Zhejiang China **Metformin:** Aarti Drugs Limited Plot No 211-213 Road No 2, GIDC Sarigam Dist Valsad Gujrat India		
API Lot No.	**Empagliflozin:** EPG220801 **Metformin:** MEF/11124163		
Description of Pack (Container closure system)	Alu-alu blister pack		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	KD-23-001	KD-23-002	KD-23-003
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	03-01-2023	03-01-2023	03-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of DML of the firm issued by CFDA China **Metformin:** Firm has submitted copy of GMP certificate issued by Food & Drugs Administration Gujrat State India valid till 20-06-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of clearance certificate specifying import of 1.5Kg Empagliflozin. The clearance certificate is issued on 07-10-2022. **Metformin:** Firm has submitted copy of commercial invoice for import of 1000kg metformin. The invoice is cleared by AD (I&E) dated 03-02-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted compliance certificate of HPLc system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC:		
Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		

M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan

115.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat**
	Name, address of Manufacturing site.	M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License was granted on 14-02-2020. Firm has submitted copy of GMP certificate based on the inspection dated 01-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 14-02-2020 specifying capsule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Tracking ID. XPT-AJE-NN5E: 20-03-2024
	Details of fee submitted	PKR 30,000/-: 12-02-2024
	The proposed proprietary name / brand name	**LANSOGEN 60 mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole (as dual delayed release pellets)…….60mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant capsule **USFDA** Approved
	For generic drugs (me-too status)	Razodex Capsule by Getz Pharma
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Razodex Capsule of Getz Pharma. Firm has submitted results of CDP for their product against Razodex Capsule of Getz Pharma.

	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.		
API Lot No.	DLP954		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DDT004	DDT005	DDT006
Batch Size	1000 Capsule	1000 Capsule	1000 Capsule
Manufacturing Date	06-2023	06-2023	06-2023
Date of Initiation	14-06-2023	15-06-2023	16-06-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 14-06-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 06-04-2023 specifying purchase of 50Kg dexlansoprazole pellets 22.5% by Seraph pharma
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm submitted that their HPLC system is not 21 CFR compliant therefore the audit trail reports are not applicable.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Sr. No	Shortcoming	Response by the firm
1.	Submit loan letter from Seraph pharma because the submitted commercial invoice is for Seraph pharma	Firm has submitted copy of loan letter

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

116.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat**
	Name, address of Manufacturing site.	M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License was granted on 14-02-2020. Firm has submitted copy of GMP certificate based on the inspection dated 01-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 14-02-2020 specifying capsule (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. EYA-AT3-UM77: 26-03-2024
	Details of fee submitted	PKR 30,000/-: 30-01-2024
	The proposed proprietary name / brand name	**VONOGEN 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Vonoprazan (as fumarate)……10mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(PMDA Japan** Approved)
	For generic drugs (me-too status)	Voniza Tablet by Hilton
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co. Ltd. Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Vonocel Tablet of Seraph Pharma. Firm has submitted results of CDP for their product against Vonocel Tablet of Seraph Pharma.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Jiangxi Synergy Pharmaceutical Co. Ltd. Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province China.		
API Lot No.	104-20220707BD		
Description of Pack (Container closure system)	Alu-alu blister pack		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	VGT001	VGT002	VGT003
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	06-2023	06-2023	06-2023
Date of Initiation	23-06-2023	23-06-2023	23-06-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of written confirmation for active substances exported to EU (No. JX200001) issued by Jiangxi Food and Drug Administration dated 20-11-2020. The drug manufacturing license of the firm is verified from SFDA official website. The SFDA official website specifies Jiangxi Tonghe Pharmaceutical Co., Ltd. As the name of Pharmaceutical manufacturing company (Number Gan20160125) having the same address as that of Jiangxi Synergy
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate of M/s Seraph pharma specifying import of 10Kg vonoprazan fumarate. The invoice is cleared by AD (I&E) DRAP dated 02-03-2023.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted HPLC audit trail reports and 21 CFR compliance certificate
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm
1.	Submit specifications of the drug substance from drug product manufacturer in section 3.2.S.4.1	Submitted
2.	Submit analytical procedure of the drug substance from drug product manufacturer in section 3.2.S.4.2.	Submitted
3.	Submit verification studies of the analytical procedure for testing of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
4.	Submit loan letter from Seraph pharma because the submitted commercial invoice is for Seraph pharma.	Firm has submitted copy of loan letter

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

117.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat**
	Name, address of Manufacturing site.	M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License was granted on 14-02-2020.

		Firm has submitted copy of GMP certificate based on the inspection dated 01-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 14-02-2020 specifying capsule (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. V4N-JUR-7EQA: 26-03-2024
	Details of fee submitted	PKR 30,000/-: 30-01-2024
	The proposed proprietary name / brand name	**VONOGEN 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Vonoprazan (as fumarate)……20mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(PMDA Japan** Approved)
	For generic drugs (me-too status)	Voniza Tablet by Hilton
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co. Ltd. Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process

		and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Vonocel Tablet of Seraph Pharma. Firm has submitted results of CDP for their product against Vonocel Tablet of Seraph Pharma.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA

Manufacturer of API	Jiangxi Synergy Pharmaceutical Co. Ltd. Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province China.		
API Lot No.	104-20220707BD		
Description of Pack (Container closure system)	Alu-alu blister pack		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	VGT004	VGT005	VGT006
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	06-2023	06-2023	06-2023
Date of Initiation	26-06-2023	26-06-2023	26-06-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of written confirmation for active substances exported to EU (No. JX200001) issued by Jiangxi Food and Drug Administration dated 20-11-2020. The drug manufacturing license of the firm is verified from SFDA official website. The SFDA official website specifies Jiangxi Tonghe Pharmaceutical Co., Ltd. As the name of Pharmaceutical manufacturing company (Number Gan20160125) having the same address as that of Jiangxi Synergy
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate of M/s Seraph pharma specifying import of 10Kg vonoprazan fumarate. The invoice is cleared by AD (I&E) DRAP dated 02-03-2023.

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

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm
1.	Submit specifications of the drug substance from drug product manufacturer in section 3.2.S.4.1	Submitted
2.	Submit analytical procedure of the drug substance from drug product manufacturer in section 3.2.S.4.2.	Submitted
3.	Submit verification studies of the analytical procedure for testing of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
4.	Submit loan letter from Seraph pharma because the submitted commercial invoice is for Seraph pharma.	Firm has submitted copy of loan letter

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

118.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat**
	Name, address of Manufacturing site.	M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License was granted on 14-02-2020. Firm has submitted copy of GMP certificate based on the inspection dated 01-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 14-02-2020 specifying Penem Injection section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. TDQ-WGV-YVR9: 01-03-2024

	Details of fee submitted	PKR 30,000/-: 30-01-2024
	The proposed proprietary name / brand name	**Mi-PENEM Injection 2g**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem Trihydrate eq.to meropenem….2g (Blended with sodium carbonate)
	Pharmaceutical form of applied drug	White to almost white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	Shenzhen Haibin Pharmaceutical Co., Ltd No. 2003, Shenyan Road, Yantian District, Shenzhen City, Guangdong Province, People's Republic of China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Meronem 2g Injection.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Shenzhen Haibin Pharmaceutical Co., Ltd No. 2003, Shenyan Road, Yantian District, Shenzhen City, Guangdong Province, People's Republic of China		
API Lot No.	8MT2211102		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NMT-001	NMT-002	NMT-003
Batch Size	250 vials	250 vials	250 vials
Manufacturing Date	05-2023	05-2023	05-2023
Date of Initiation	19-05-2023	19-05-2023	19-05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of manufacturing license (No. Yue20160126) valid till 08-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 19-12-2022 specifying import of 60Kg meropenem for injection.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm
1.	Submit differential fee since the applied formulation is not yet registered in Pakistan.	Firm has not differential fee
2.	Submit specifications of the drug substance from drug product manufacturer in section 3.2.S.4.1	Submitted
3.	Submit analytical procedure of the drug substance from drug product manufacturer in section 3.2.S.4.2.	Submitted
4.	Submit verification studies of the analytical procedure for testing of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted

5.	Submit details of the product against which pharmaceutical equivalence is conducted since the applied formulation is not yet registered in Pakistan.	Firm has submitted details of reference product against which pharmaceutical equivalence was conducted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit 45,000/- differential fee, since the applied formulation is a new drug as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

119.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat**
	Name, address of Manufacturing site.	M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License was granted on 14-02-2020. Firm has submitted copy of GMP certificate based on the inspection dated 01-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 14-02-2020 specifying Tablet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. NN7-RNX-EYV2: 11-03-2024
	Details of fee submitted	PKR 30,000/-: 30-01-2024
	The proposed proprietary name / brand name	**SEVELGEN 400mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Sevelamer Carbonate…….. 400mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Drugs for treatment of hyperkalemia and hyperphosphatemia
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Sevela Tablet by Hilton
	Name and address of API manufacturer.	Suleshvari Pharma Plot No: 6012/1, GIDC Estate,

		Ankleshwar – 393002 Dist.: Bharuch (Gujarat), India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Neovel Tablet of Seraph Pharma. Firm has submitted results of kinetic binding studies for their product against Neovel Tablet of Seraph Pharma.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Suleshvari Pharma Plot No: 6012/1, GIDC Estate, Ankleshwar – 393002 Dist.: Bharuch (Gujarat), India.
API Lot No.	23/SVMC/004
Description of Pack (Container closure system)	Alu-alu blister pack
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	SM031	SM032	SM033
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	07-2023	07-2023	07-2023
Date of Initiation	12-07-2023	12-07-2023	12-07-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Food & Drugs Control Administration Gujrat State India valid till 26-09-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate of M/s Seraph pharma specifying import of 100Kg Sevelamer carbonate dated 06-03-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted HPLC audit trail reports and 21 CFR compliance certificate
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm
1.	Submit loan letter from Seraph pharma because the submitted commercial invoice is for Seraph pharma.	Firm has submitted copy of loan letter

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

120.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat**
	Name, address of Manufacturing site.	M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License was granted on 14-02-2020. Firm has submitted copy of GMP certificate based on the inspection dated 01-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 14-02-2020 specifying Tablet (General) section.

	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. S47-86T-M6SR: 18-03-2024
	Details of fee submitted	PKR 30,000/-: 30-01-2024
	The proposed proprietary name / brand name	**SEVELGEN 800mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Sevelamer Carbonate…….. 800mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Drugs for treatment of hyperkalemia and hyperphosphatemia
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Sevela Tablet by Hilton
	Name and address of API manufacturer.	Suleshvari Pharma Plot No: 6012/1, GIDC Estate, Ankleshwar – 393002 Dist.: Bharuch (Gujarat), India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials,

		container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Neovel Tablet of Seraph Pharma. Firm has submitted results of kinetic binding studies for their product against Neovel Tablet of Seraph Pharma.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA

Manufacturer of API	Suleshvari Pharma Plot No: 6012/1, GIDC Estate, Ankleshwar – 393002 Dist.: Bharuch (Gujarat), India.		
API Lot No.	23/SVMC/004		
Description of Pack (Container closure system)	Alu-alu blister pack		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	SM034	SM035	SM036
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	07-2023	07-2023	07-2023
Date of Initiation	12-07-2023	12-07-2023	12-07-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Food & Drugs Control Administration Gujrat State India valid till 26-09-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate of M/s Seraph pharma specifying import of 100Kg Sevelamer carbonate dated 06-03-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted HPLC audit trail reports and 21 CFR compliance certificate
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm

1.	Submit loan letter from Seraph pharma because the submitted commercial invoice is for Seraph pharma.	Firm has submitted copy of loan letter

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

121.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat**
	Name, address of Manufacturing site.	M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License was granted on 14-02-2020. Firm has submitted copy of GMP certificate based on the inspection dated 01-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 14-02-2020 specifying Tablet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. 8BV-L7Z-DTV9: 19-03-2024
	Details of fee submitted	PKR 30,000/-: 30-01-2024
	The proposed proprietary name / brand name	**PARADOL D 37.5/325mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tramadol HCl……37.5 mg Paracetamol……. 325 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Opioids in combination with non-opioid analgesics
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(MHRA** Approved)
	For generic drugs (me-too status)	Tonoflex-P Tablet by Sami
	Name and address of API manufacturer.	**Paracetamol:** Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan. **Tramadol:** M/s. VIRUPAKSHA ORGANIC LIMITED, Plot No. B-4 IDA, Gandhinagar, Hyderabad -500037, Telengana, India,

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Tonoflex-P Tablet of Sami. Firm has submitted results of kinetic binding studies for their product against Tonoflex-P Tablet of Sami.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Paracetamol:** Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan. **Tramadol:** M/s. VIRUPAKSHA ORGANIC LIMITED, Plot No. B-4 IDA, Gandhinagar, Hyderabad -500037, Telengana, India.
API Lot No.	**Paracetamol:** PGS21-103 **Tramadol:** BTDHC0821096
Description of Pack (Container closure system)	Alu-alu blister pack
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PT001	PT002	PT003
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	06-2023	06-2023	06-2023
Date of Initiation	03-06-2023	03-06-2023	03-06-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Paracetamol:** Firm has submitted copy of GMP certificate issued on the basis of inspection dated 03-03-2023 **Tramadol:** Firm has submitted copy of GMP certificate issued by Drug Control Administration government of Telangana dated 27-03-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Paracetamol:** Firm has submitted copy of commercial invoice dated 30-11-2021 specifying 540kg paracetamol by Biogen Pharma **Tramadol:** Firm has submitted copy of ADC attested commercial invoice dated 23-10-2021 specifying import of 100kg tramadol by Biogen Pharma
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted HPLC audit trail reports and 21 CFR compliance certificate
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm
1.	Submit details including brand name and manufacturer of the comparator product against which pharmaceutical equivalence and CDP studies are conducted.	Firm has submitted details of comparator product.
2.	Submit valid GMP certificate of both API manufacturer.	**Paracetamol:** Firm has submitted copy of GMP certificate issued on the basis of inspection dated 03-03-2023 **Tramadol:** Firm has submitted copy of GMP certificate issued by Drug Control Administration government of Telangana dated 27-03-2019.
3.	Submit loan letter from Biogen pharma because the submitted commercial invoice is for Biogen pharma.	Firm has submitted copy of loan letter

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

122.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat**
	Name, address of Manufacturing site.	M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License was granted on 14-02-2020. Firm has submitted copy of GMP certificate based on the inspection dated 01-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 14-02-2020 specifying Tablet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. 8BV-L7Z-DTV9: 19-03-2024
	Details of fee submitted	PKR 30,000/-: 30-01-2024
	The proposed proprietary name / brand name	**PARADOL D 75/650mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tramadol HCl……75mg Paracetamol……. 650mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Opioids in combination with non-opioid analgesics
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(MHRA** Approved)
	For generic drugs (me-too status)	Tonoflex-P Tablet by Sami
	Name and address of API manufacturer.	**Paracetamol:** Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan. **Tramadol:** M/s. VIRUPAKSHA ORGANIC LIMITED, Plot No. B-4 IDA, Gandhinagar, Hyderabad -500037, Telengana, India,
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	~~Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Neovel Tablet of Seraph Pharma.~~ ~~Firm has submitted results of kinetic binding studies for their product against Neovel Tablet of Seraph Pharma.~~
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Paracetamol:** Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan. **Tramadol:** M/s. VIRUPAKSHA ORGANIC LIMITED, Plot No. B-4 IDA, Gandhinagar, Hyderabad -500037, Telengana, India.		
API Lot No.	**Paracetamol:** PGS21-103 **Tramadol:** BTDHC0821096		
Description of Pack (Container closure system)	Alu-alu blister pack		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PT004	PT005	PT006
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	06-2023	06-2023	06-2023
Date of Initiation	03-06-2023	03-06-2023	03-06-2023
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Paracetamol:** Firm has submitted copy of GMP certificate issued on the basis of inspection dated 03-03-2023 **Tramadol:** Firm has submitted copy of GMP certificate issued by Drug Control Administration government of Telangana dated 27-03-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Paracetamol:** Firm has submitted copy of commercial invoice dated 30-11-2021 specifying 540kg paracetamol by Biogen Pharma **Tramadol:** Firm has submitted copy of ADC attested commercial invoice dated 23-10-2021 specifying import of 100kg tramadol by Biogen Pharma
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted HPLC audit trail reports and 21 CFR compliance certificate
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm
1.	Submit details including brand name and manufacturer of the comparator product against which pharmaceutical equivalence and CDP studies are conducted.	Firm has submitted details of comparator product.
2.	Submit valid GMP certificate of both API manufacturer.	**Paracetamol:** Firm has submitted copy of GMP certificate issued on the basis of inspection dated 03-03-2023 **Tramadol:** Firm has submitted copy of GMP certificate issued by Drug Control Administration government of Telangana dated 27-03-2019.
3.	Submit loan letter from Biogen pharma because the submitted commercial invoice is for Biogen pharma.	Firm has submitted copy of loan letter

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

123.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat**
	Name, address of Manufacturing site.	M/s Biogen Life Scieces 8-KM, Chak Beli Road, Rawat
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License was granted on 14-02-2020. Firm has submitted copy of GMP certificate based on the inspection dated 01-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Soft gel capsule general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. 8UA-A7G-ZLXM: 21-02-2024
	Details of fee submitted	PKR 30,000/-: 19-12-2023
	The proposed proprietary name / brand name	**ALTREZAM 40 mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gel capsule Contains: Isotretinoin……40mg
	Pharmaceutical form of applied drug	Soft Gelatin Capsule
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Maxinoin Capsule by Maxitech (Reg # 108920)
	Name and address of API manufacturer.	Chongqing Huapont Shengchem Pharmaceutical Co. Ltd No. 666 Rongjun Road, Nanjin Avenue, Hechuan District, Changqin China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches

	(Conditions & duration of Stability studies)	of drug substance
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Moxinoin 40mg Capsule of Maxitech. Firm has submitted results of CDP for their product against Moxinoin 40mg Capsule.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Chongqing Huapont Shengchem Pharmaceutical Co. Ltd No. 666 Rongjun Road, Nanjin Avenue, Hechuan District, Changqin China.		
API Lot No.	20220418		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-012	T-013	T-014
Batch Size	1000 Capsule	1000 Capsule	1000 Capsule
Manufacturing Date	04-2023	04-2023	04-2023
Date of Initiation	17-04-2023	17-04-2023	17-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Drug Import License dated 11-02-2026
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm
1.	Submit details including brand name and manufacturer of the comparator product against which pharmaceutical equivalence and CDP studies are conducted.	Submitted by the firm
2.	Submit valid GMP certificate of API manufacturer.	Firm has submitted copy of written confirmation of active substance exported to EU specifying valid license of the firm issued by Chongqing Food and Drug Administration. The License of the firm is also verified online (License No. Yu 20150075) valid till 09-08-2025.
3.	Submit evidence of import of API / clearance certificate.	Firm has submitted copy of Drug Import License dated 11-02-2022.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

124.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies ampoule section SVP (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27869: 30-10-2023
	Details of fee submitted	PKR 30,000/-: 15-11-2023
	The proposed proprietary name / brand name	**3D Injection 7.5mg/mL (Oral / IM)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule Contains: Cholecalciferol……7.5mg (300000IU)
	Pharmaceutical form of applied drug	Sterile clear and colourless oily solution filled in glass ampoules

	Pharmacotherapeutic Group of (API)	Vitamin
	Reference to Finished product specifications	BP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**AIFA** Italy Approved
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	Sichuan Yuxin Pharmaceutical Co., Ltd. No. 51, West Section of Changjiang Road, Shifang Economic Development Zone (South District) Shifang city, Sichuan Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against vitamin D3 300000 IU injection
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and validation studies of the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Sichuan Yuxin Pharmaceutical Co., Ltd. No. 51, West Section of Changjiang Road, Shifang Economic Development Zone (South District) Shifang city, Sichuan Province China.
API Lot No.	CH22041003
Description of Pack	Glass ampoule

(Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	24-03-2023	24-03-2023	24-03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML issued by CFDA China.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice and Goods Declaration
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Firm has submitted 30,000 fee while no me-too is available for this product.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit 45,000/- differential fee, since the applied formulation is a new drug as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.

125.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar

		Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Evidence of approval of manufacturing facility	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. Z95-AB4-TQEU: 18-04-2024
	Details of fee submitted	PKR 30,000/-: 03-04-2024
	The proposed proprietary name / brand name	**CIPROVA 250mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin (as hydrochloride) ……250mg
	Pharmaceutical form of applied drug	white oblong film coated tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cipro Tablet 250mg by Bayer HealthCare Pharmaceuticals Inc. USA (**USFDA** Approved)
	For generic drugs (me-too status)	Ciproxin Tablet 250mg of M/s Bayer Pakistan (Pvt) Limited (Reg # 010118)
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Ciptec tablet of Seraph. Firm has submitted results of CDP for their product against Ciptec tablet of Seraph
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00510011/022/2023		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003

Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	12-2023	12-2023	12-2023
Date of Initiation	09-12-2023	09-12-2023	09-12-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 22-11-2022. The GMP certificate was granted based on inspection dated 18-11-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice for 5Kg Ciprofloxacin hydrochloride dated 01-12-2023 from Pharmagen.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted by the firm
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit 6 month's stability study data since the submitted data is for 3 months only.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Board authorized its Chairman for issuance of Registration Letter upon submission of 6th month stability study data.**

126.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section

		• Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Evidence of approval of manufacturing facility	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. 21Y-Z5J-U241: 17-04-2024
	Details of fee submitted	PKR 30,000/-: 03-04-2024
	The proposed proprietary name / brand name	**CIPROVA 500MG TABLETS**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin (as hydrochloride) ……500mg
	Pharmaceutical form of applied drug	white oblong film coated tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cipro Tablet 250mg by Bayer HealthCare Pharmaceuticals Inc. USA (**USFDA** Approved)
	For generic drugs (me-too status)	Ciproxin Tablet 250mg of M/s Bayer Pakistan (Pvt) Limited (Reg # 010118)
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form,

		manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Ciptec tablet of Seraph. Firm has submitted results of CDP for their product against Ciptec tablet of Seraph
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00510011/022/2023		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	12-2023	12-2023	12-2023
Date of Initiation	09-12-2023	09-12-2023	09-12-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 22-11-2022. The GMP certificate was granted based on inspection dated 18-11-2022.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice for 5Kg Ciprofloxacin hydrochloride dated 01-12-2023 from Pharmagen.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted by the firm
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit 6 month's stability study data since the submitted data is for 3 months only.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Board authorized its Chairman for issuance of Registration Letter upon submission of 6th month stability study data.**

127.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Evidence of approval of manufacturing facility	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. PS5-N5B-RGGN : 17-04-2024
	Details of fee submitted	PKR 30,000/-: 21-03-2024
	The proposed proprietary name / brand name	**AZINEM 250mg tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Azithromycin (as dihydrate)……250mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Macrolides
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	(**USFDA** Approved)
	For generic drugs (me-too status)	Orzit Tablet 250mg of M/s Martin Dow (Reg # 057294)
	Name and address of API manufacturer.	M/s Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative	Firm has submitted results of pharmaceutical

	Dissolution Profile	equivalence for the quality tests for their product against Azikam Tablet of Seraph pharma. Firm has submitted results of CDP in three dissolution medium for their product against Azikam Tablet of Seraph pharma
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan		
API Lot No.	AZM2311001		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	11-2023	11-2023	11-2023
Date of Initiation	16-11-2023	16-11-2023	16-11-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated 09-03-2023 issued on the basis of inspection dated 03-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 10Kg Azithromycin dihydrate dated 13-11-2023.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with UV spectra, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable. Our HPLC systems are not 21 CFR compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit 6 month's stability study data since the submitted data is for 3 months only.

Decision: Approved.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Board authorized its Chairman for issuance of Registration Letter upon submission of 6th month stability study data.**		
128.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Evidence of approval of manufacturing facility	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. 223-3AH-HXED: 17-04-2024
	Details of fee submitted	PKR 30,000/-: 21-03-2024
	The proposed proprietary name / brand name	**AZINEM 500mg tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Azithromycin (as dihydrate)……500mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Macrolides
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	(**USFDA** Approved)
	For generic drugs (me-too status)	Orzit Tablet of M/s Martin Dow
	Name and address of API manufacturer.	M/s Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Azikam Tablet of Seraph pharma. Firm has submitted results of CDP in three dissolution medium for their product against Azikam Tablet of Seraph pharma
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan
API Lot No.	AZM2311001
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	11-2023	11-2023	11-2023
Date of Initiation	16-11-2023	16-11-2023	16-11-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated 09-03-2023 issued on the basis of inspection dated 03-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 10Kg Azithromycin dihydrate dated 13-11-2023.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with UV spectra, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable. Our HPLC systems are not 21 CFR compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit 6 month's stability study data since the submitted data is for 3 months only.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Board authorized its Chairman for issuance of Registration Letter upon submission of 6th month stability study data.**

M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore

129.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19212: 02-08-2023
	Details of fee submitted	PKR 30,000/-: 27-04-2023
	The proposed proprietary name / brand name	**CEFOSS 250mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftizoxime Soidum …250mg
	Pharmaceutical form of applied drug	Powder for injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be confirmed
	For generic drugs (me-too status)	Cefizox Injection by Barrett Hodgson
	Name and address of API manufacturer.	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd. West Side of Yanbin Road, Economic Development Zone, Feixian, Linyi, Shandong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug

		substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone II conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd. West Side of Yanbin Road, Economic Development Zone, Feixian, Linyi, Shandong, China		
API Lot No.	12C0302104005		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-66	TR-CEP-67	TR-CEP-68
Batch Size	1719 vials	1719 vials	1719 vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	17-09-2021	17-09-2021	17-09-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	

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

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
4.	Submit COA of reference standard used in the analysis of drug substance.	
5.	Submit stability study data of 3 batches of API as per zone IV-A conditions.	
6.	Specify the fill weight of the product per vial.	
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
8.	Submit report of pharmaceutical equivalence studies.	
9.	Submit preservative effectiveness studies	
	Submit microbial attributes of the drug product	
10	Submit compatibility studies in section 3.2.P.2.6	
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
11.	Submit BMR of three stability batches.	

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

130.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19211: 02-08-2023
	Details of fee submitted	PKR 30,000/-: 27-04-2023
	The proposed proprietary name / brand name	**CEFOSS 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftizoxime Soidum …1g
	Pharmaceutical form of applied drug	Powder for injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be confirmed
	For generic drugs (me-too status)	Cefizox Injection by Barrett Hodgson
	Name and address of API manufacturer.	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd. West Side of Yanbin Road, Economic Development Zone, Feixian, Linyi, Shandong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone II conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative	

	Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd. West Side of Yanbin Road, Economic Development Zone, Feixian, Linyi, Shandong, China		
API Lot No.	12C0302104005		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-10	TR-CEP-11	TR-CEP-12
Batch Size	1080 vials	1080 vials	1080 vials
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	09-07-2021	09-07-2021	09-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	

4.	Submit COA of reference standard used in the analysis of drug substance.	
5.	Submit stability study data of 3 batches of API as per zone IV-A conditions.	
6.	Specify the fill weight of the product per vial.	
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
8.	Submit report of pharmaceutical equivalence studies.	
9.	Submit preservative effectiveness studies	
	Submit microbial attributes of the drug product	
10	Submit compatibility studies in section 3.2.P.2.6	
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
11.	Submit BMR of three stability batches.	

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

131.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5097: 22-02-2023
	Details of fee submitted	PKR 30,000/-: 10-01-2022
	The proposed proprietary name / brand name	**CURAGON 125mg/5ml Dry Powder Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Reconstituted Suspension Contains: Cephalexin……125mg
	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Ceporex suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
API Lot No.	
Description of Pack (Container closure system)	Glass bottle
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months)

	Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-30	TR-CEP-31	TR-CEP-32
Batch Size	900 bottles	900 bottles	900 bottles
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	04-08-2021	04-08-2021	04-08-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
5.	Justify the use of compacted API to manufacture suspension	
6.	Submit COA of reference standard used in the analysis of drug substance.	
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
8.	Submit report of pharmaceutical equivalence and CDP studies.	
9.	Submit preservative effectiveness studies	
	Submit microbial attributes of the drug product	
10	Submit compatibility studies in section 3.2.P.2.6	
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in	

	proper sequence with tagging to differentiate between data of each time point and batch.	
11.	Submit BMR of three stability batches.	

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

132.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4883: 20-02-2023
	Details of fee submitted	PKR 30,000/-: 10-01-2022
	The proposed proprietary name / brand name	**CURAGON 250mg/5ml Dry Powder Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Reconstituted Suspension Contains: Cephalexin……250mg
	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Ceporex suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-33	TR-CEP-34	TR-CEP-35
Batch Size	900 bottles	900 bottles	900 bottles
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	04-08-2021	04-08-2021	04-08-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
5.	Justify the use of compacted API to manufacture suspension	
6.	Submit COA of reference standard used in the analysis of drug substance.	
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
8.	Submit report of pharmaceutical equivalence and CDP studies.	
9.	Submit preservative effectiveness studies	
	Submit microbial attributes of the drug product	
10	Submit compatibility studies in section 3.2.P.2.6	
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
11.	Submit BMR of three stability batches.	

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

133.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020

	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 849: 10-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**ROXI 500mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cefadroxil …500mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Duricef suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including

		its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	~~TR-CEP-21~~	~~TR-CEP-22~~	~~TR-CEP-23~~
Batch Size	~~1000 bottles~~	~~1000 bottles~~	~~1000 bottles~~
Manufacturing Date	~~07-2021~~	~~07-2021~~	~~07-2021~~
Date of Initiation	~~29-07-2021~~	~~29-07-2021~~	~~29-07-2021~~
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	

2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
5.	Specify whether the drug substance used is compacted or micronized	
6.	Submit COA of reference standard used in the analysis of drug substance.	
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
8.	Submit report of pharmaceutical equivalence and CDP studies.	
9.	Submit data in section 3.2.P.8.1 as per the CTD guidance document	
	Submit stability data sheet of three stability batches	
10	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
10.	Submit BMR of three stability batches.	

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

134.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 857: 10-01-2023

	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**ROXI 125mg/5ml 60ml Dry Powder Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Reconstituted Suspension Contains: Cefadroxil Monohydrate…125mg
	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be confirmed
	For generic drugs (me-too status)	Duricef suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
STABILITY STUDY DATA		
Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.	

API Lot No.			
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-18	TR-CEP-19	TR-CEP-20
Batch Size	600 bottles	600 bottles	600 bottles
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	29-07-2021	29-07-2021	29-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting	
2.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
3.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
4.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
5.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
6.	Specify whether the drug substance used is compacted or micronized	

7.	Submit COA of reference standard used in the analysis of drug substance.	
8.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
9.	Submit report of pharmaceutical equivalence and CDP studies.	
	Submit preservative effectiveness studies	
10	Submit microbial attributes of the drug product	
10.	Submit compatibility studies in section 3.2.P.2.6	
11.	Justify why your analytical procedure is different from USP monograph.	
12	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
13	Submit BMR of three stability batches.	

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

135.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 857: 10-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**ROXI 250mg/5ml 60ml Dry Powder Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Reconstituted Suspension Contains: Cefadroxil Monohydrate…250mg
	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Duricef suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
API Lot No.	
Description of Pack (Container closure system)	Glass bottle
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months)

	Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-21	TR-CEP-22	TR-CEP-23
Batch Size	1000 bottles	1000 bottles	1000 bottles
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	29-07-2021	29-07-2021	29-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
5.	Specify whether the drug substance used is compacted or micronized	
6.	Submit COA of reference standard used in the analysis of drug substance.	
7.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
8.	Submit report of pharmaceutical equivalence and CDP studies.	
9.	Submit preservative effectiveness studies	
	Submit microbial attributes of the drug product	
10	Submit compatibility studies in section 3.2.P.2.6	
10.	Justify why your analytical procedure is different from USP monograph.	

11.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
12	Submit BMR of three stability batches.	

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

136.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 850: 10-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**VELOSEM 125mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Reconstituted Suspension Contains: Cephradine…125mg
	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be confirmed
	For generic drugs (me-too status)	Velosef 125mg suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties,

		solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-15	TR-CEP-16	TR-CEP-17
Batch Size	600 bottles	600 bottles	600 bottles
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	26-07-2021	26-07-2021	26-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting	
2.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
3.	The method of analysis of the drug substance of Pharmagen Limited submitted in section 3.2.S.4.2 is different from BP as well as USP monograph. Justification is required in this regard.	
4.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
5.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
6.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
7.	Specify whether the drug substance used is cephradine or cephradine monohydrate	
8.	Justify how cephradine plain is used to manufacture cephradine suspension instead of using cephradine micronized.	
9.	Submit COA of cephalexin reference standard which is also required in the analysis of drug substance.	
	Justify how same stability study data of cephradine API used for manufacturing of Injection and capsule is used.	
10	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
10.	Submit report of pharmaceutical equivalence studies.	
11.	Submit compatibility studies in section 3.2.P.2.6	
12	Justify why your analytical procedure is different from USP monograph.	
13	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data	

	shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
14	Submit BMR of three stability batches.	

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

137.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4882: 20-02-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**VELOSEM 250mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Reconstituted Suspension Contains: Cephradine…250mg
	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nicef Syrup 250mg/5ml **(MHRA** Approved)
	For generic drugs (me-too status)	Velosef 250mg suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00203/163/2020		
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-12	TR-CEP-13	TR-CEP-14
Batch Size	600 bottles	600 bottles	600 bottles
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	26-07-2021	26-07-2021	26-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
2.	The method of analysis of the drug substance of Pharmagen Limited submitted in section 3.2.S.4.2 is different from BP as well as USP monograph. Justification is required in this regard.	
3.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
4.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
5.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
6.	Specify whether the drug substance used is cephradine or cephradine monohydrate	
7.	Justify how cephradine plain is used to manufacture cephradine suspension instead of using cephradine micronized.	
8.	Submit COA of cephalexin reference standard which is also required in the analysis of drug substance.	
9.	Justify how same stability study data of cephradine API used for manufacturing of Injection and capsule is used.	
	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
10	Submit report of pharmaceutical equivalence studies.	
10.	Submit compatibility studies in section 3.2.P.2.6	
11.	Justify why your analytical procedure is different from USP monograph.	
12	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
13	Submit BMR of three stability batches.	

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

138.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2552: 26-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**VELOSEM 250mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cephradine…250mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cephradine capsule **(MHRA** Approved)
	For generic drugs (me-too status)	Velosef capsule by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-01	TR-CEP-02	TR-CEP-03
Batch Size	1500 capsule	1500 capsule	1500 capsule
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	02-07-2021	02-07-2021	02-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	

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

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
1.	The method of analysis of the drug substance of Pharmagen Limited submitted in section 3.2.S.4.2 is different from BP as well as USP monograph. Justification is required in this regard.	
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
5.	Specify whether the drug substance used is cephradine or cephradine monohydrate	
6.	Justify how cephradine plain is used to manufacture cephradine capsule instead of using cephradine compacted.	
7.	Submit COA of cephalexin reference standard which is also required in the analysis of drug substance.	
	Justify how same stability study data of cephradine API used for manufacturing of Injection and capsule is used.	
8.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
9.	Submit report of pharmaceutical equivalence as well as CDP studies.	
10	Justify why your analytical procedure is different from USP monograph.	
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
11.	Submit BMR of three stability batches.	

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

139.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2553: 26-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**VELOSEM 500mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cephradine…500mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cephradine capsule **(MHRA** Approved)
	For generic drugs (me-too status)	Velosef capsule by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-01	TR-CEP-02	TR-CEP-03
Batch Size	1500 capsule	1500 capsule	1500 capsule
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	02-07-2021	02-07-2021	02-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
1.	The method of analysis of the drug substance of Pharmagen Limited submitted in section 3.2.S.4.2 is different from BP as well as USP monograph. Justification is required in this regard.	
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board	
4.	Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.	
5.	Specify whether the drug substance used is cephradine or cephradine monohydrate	
6.	Justify how cephradine plain is used to manufacture cephradine capsule instead of using cephradine compacted.	
7.	Submit COA of cephalexin reference standard which is also required in the analysis of drug substance.	
	Justify how same stability study data of cephradine API used for manufacturing of Injection and capsule is used.	
8.	Submit drug excipient compatibility studies, since your qualitative composition is different from that of reference product.	
9.	Submit report of pharmaceutical equivalence as well as CDP studies.	
10	Justify why your analytical procedure is different from USP monograph.	
10.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
11.	Submit BMR of three stability batches.	

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

140.	**Name, address of Applicant / Mar keting Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections:

		• Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	1A1-UUZ-HGNG: 09-01-2024
	Details of fee submitted	PKR 30,000/-: 11-12-2023
	The proposed proprietary name / brand name	**TACT 90mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Reconstituted Suspnesion contains: Ceftibuten Dihydrate eq. to Ceftibuten ... 90mg
	Pharmaceutical form of applied drug	Powder for solution for injection
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cedax Suspension (USFDA Approved) **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	Xigris Suspension by Wilshire
	Name and address of API manufacturer.	Danuka Lboratories Limited , 7Km Old Manesar Road, Village Mohammedpur Gurgaon , Haryana
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Danuka Lboratories Limited , 7Km Old Manesar Road, Village Mohammedpur Gurgaon , Haryana		
API Lot No.			
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-78	TR-CEP-79	TR-CEP-80
Batch Size	875 Bottles	875 Bottles	875 Bottles
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	21-09-2021	21-09-2021	21-09-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Food and Drug Administration Haryana India dated 04-03-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
2.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	
3.	Submit COA of relevant batch of API from API manufacturer as well as from drug product manufacturer.	
4.	Submit COA of reference standard used in the analysis of drug substance.	
5.	Submit evidence of requisite storage facility to store cephradine at refrigerated conditions within the raw material warehouse.	
6.	Submit drug-excipient compatibility studies since your formulation is qualitatively different from reference product.	
7.	Submit pharmaceutical equivalence in section 3.2.P.2.2.1	
8.	Submit data of compatibility of the drug product in section 3.2.P.2.5.	
9.	Submit microbiological attributes in section 3.2.P.2.6.	
	Submit preservative effectiveness studies.	
10.	Submit dispensed weight per bottle for the applied product and also complete calculation how that fill weight is equivalent to the content of ceftibuten per 5ml as per the label claim.	
11.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
12.	Submit BMR of three stability batches.	

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

141.	**Name, address of Applicant / Mar keting Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 858: 10-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**VELOSEM 250mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cephradine L-Arginine…250mg
	Pharmaceutical form of applied drug	Powder for solution for injection
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NA
	For generic drugs (me-too status)	Velosef Injection by GSK
	Name and address of API manufacturer.	Pharmagen Limited Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative	

	Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Pharmagen Limited Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
2.	Submit valid GMP certificate / inspection report of the srug product manufacturer.	
3.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures	

	used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
4.	Specify whether the drug substance is cephradine or cephradine monohydrate.	
5.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	
6.	Submit COA of relevant batch of API from API manufacturer as well as from drug product manufacturer.	
7.	Submit COA of reference standard used in the analysis of drug substance.	
8.	Submit evidence of requisite storage facility to store cephradine at refrigerated conditions within the raw material warehouse.	
9.	Submit data in section 3.2.P.1 as per CTD guidance document.	
10.	Submit pharmaceutical equivalence in section 3.2.P.2.2.1	
11.	Submit data of compatibility of the drug product in section 3.2.P.2.5.	
12.	Submit microbiological attributes in section 3.2.P.2.6.	
13.	Submit proper fill weight per vial for the applied product and also complete calculation how that fill weight is equivalent to the content of cephradine as per the label claim.	
14.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
15.	Submit BMR of three stability batches.	

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

142.	**Name, address of Applicant / Mar keting Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section. • Dry powder for suspension (cephalosporin) section.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2554: 26-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**VELOSEM 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cephradine L-Arginine…500mg
	Pharmaceutical form of applied drug	Powder for solution for injection
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NA
	For generic drugs (me-too status)	Velosef Injection by GSK
	Name and address of API manufacturer.	Pharmagen Limited Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-07	TR-CEP-08	TR-CEP-09
Batch Size	1100 vials	1100 vials	1100 vials
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	09-07-2021	09-07-2021	09-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
2.	Submit valid GMP certificate / inspection report of the srug product manufacturer.	
3.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that “Copies of the Drug	

	substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
4.	Specify whether the drug substance is cephradine or cephradine monohydrate.	
5.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	
6.	Submit COA of relevant batch of API from API manufacturer as well as from drug product manufacturer.	
7.	Submit COA of reference standard used in the analysis of drug substance.	
8.	Submit evidence of requisite storage facility to store cephradine at refrigerated conditions within the raw material warehouse.	
9.	Submit data in section 3.2.P.1 as per CTD guidance document.	
10.	Submit pharmaceutical equivalence in section 3.2.P.2.2.1	
11.	Submit data of compatibility of the drug product in section 3.2.P.2.5.	
12.	Submit microbiological attributes in section 3.2.P.2.6.	
13.	Submit proper fill weight per vial for the applied product and also complete calculation how that fill weight is equivalent to the content of cephradine as per the label claim.	
14.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
15.	Submit BMR of three stability batches.	

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

143.	**Name, address of Applicant / Mar keting Authorization Holder**	**M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of leter of grant of additional section dated 22-12-2020 which specifies following sections: • Dry powder for injection (Cephalosporin) section. • Capsule (Cephalosporin) section.

		• Dry powder for suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 851: 10-01-2023
	Details of fee submitted	PKR 30,000/-: 28-11-2022
	The proposed proprietary name / brand name	**VELOSEM 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cephradine L-Arginine…1g
	Pharmaceutical form of applied drug	Powder for solution for injection
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NA
	For generic drugs (me-too status)	Velosef Injection by GSK
	Name and address of API manufacturer.	Pharmagen Limited Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of

		specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Pharmagen Limited Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-CEP-10	TR-CEP-11	TR-CEP-12
Batch Size	1100 vials	1100 vials	1100 vials
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	09-07-2021	09-07-2021	09-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	
2.	Submit valid GMP certificate / inspection report of the srug product manufacturer.	

3.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
4.	Specify whether the drug substance is cephradine or cephradine monohydrate.	
5.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	
6.	Submit COA of relevant batch of API from API manufacturer as well as from drug product manufacturer.	
7.	Submit COA of reference standard used in the analysis of drug substance.	
8.	Submit evidence of requisite storage facility to store cephradine at refrigerated conditions within the raw material warehouse.	
9.	Submit data in section 3.2.P.1 as per CTD guidance document.	
10.	Submit pharmaceutical equivalence in section 3.2.P.2.2.1	
11.	Submit data of compatibility of the drug product in section 3.2.P.2.5.	
12.	Submit microbiological attributes in section 3.2.P.2.6.	
13.	Submit proper fill weight per vial for the applied product and also complete calculation how that fill weight is equivalent to the content of cephradine as per the label claim.	
14.	Submit stability study data of drug product in section 3.2.P.8 as per the 6 points checklist specified in the CTD guidance document. Moreover, the stability data shall be submitted in proper sequence with tagging to differentiate between data of each time point and batch.	
15.	Submit BMR of three stability batches.	

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

144.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan**
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license dated 11th November 2021 for following sections:

		1. Tablet (General) 2. Capsule (General) 3. Cream /ointment section (General) 4. Tablet (Hormone) 5. Dry Powder Suspension (General)
	Evidence of approval of manufacturing facility	Firm has been granted new license dated 11th November 2021 for following sections: 1. Tablet (General) 2. Capsule (General) 3. Cream /ointment section (General) 4. Tablet (Hormone) 5. Dry Powder Suspension (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. AWD-AZD-ADV4: 11-03-2024
	Details of fee submitted	PKR 30,000/-: 20-12-2023
	The proposed proprietary name / brand name	**FLIMOXIN 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contain: Levofloxacin as hemihydrate…….250 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Leflox Tablet by Getz
	Name and address of API manufacturer.	Zhejiang East-Asia Pharmaceutical Co., Ltd Coastel Industrial City, Pubagang Town, Sanmen County,Zhejiang, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Leflox Tablet of Getz. Firm has submitted CDP studies in 3 medium against Leflox Tablet of Getz
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang East-Asia Pharmaceutical Co., Ltd Coastel Industrial City, Pubagang Town, Sanmen County,Zhejiang, China		
API Lot No.	DC-004-2205017		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	17-03-2023	17-03-2023	17-03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	~~Copy of GMP Certificate on the basis of evaluation conducted on 14-06-2022 is submitted.~~
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 25-10-2022 specifying 300Kg levofloxacin dated by legacy pharma.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm
1.	Submit valid GMP certificate of API manufacturer.	
2.	Submit loan letter from Legacy Pharma since the API import documents of Legacy pharma has been submitted.	
3.	Submit complete stability study data including HPLC chromatograms, dissolution data and related analytical record since no such data has been submitted in module 3.	

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

145.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan**
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license dated 11th November 2021 for following sections: 1. Tablet (General) 2. Capsule (General) 3. Cream /ointment section (General) 4. Tablet (Hormone) 5. Dry Powder Suspension (General)
	Evidence of approval of manufacturing facility	Firm has been granted new license dated 11th November 2021 for following sections: 1. Tablet (General) 2. Capsule (General) 3. Cream /ointment section (General) 4. Tablet (Hormone) 5. Dry Powder Suspension (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID: 4PL-PG2-VU36: 11-03-2024
	Details of fee submitted	PKR 30,000/-: 21-12-2023

	The proposed proprietary name / brand name	**FLIMOXIN 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contain: Levofloxacin as hemihydrate…….500 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Leflox Tablet by Getz
	Name and address of API manufacturer.	Zhejiang East-Asia Pharmaceutical Co., Ltd Coastel Industrial City, Pubagang Town, Sanmen County,Zhejiang, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Leflox Tablet of Getz. Firm has submitted CDP studies in 3 medium against Leflox Tablet of Getz
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of

		analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang East-Asia Pharmaceutical Co., Ltd Coastel Industrial City, Pubagang Town, Sanmen County,Zhejiang, China		
API Lot No.	DC-004-2205017		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-04	T-05	T-06
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	17-03-2023	17-03-2023	17-03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	~~Copy of GMP Certificate on the basis of evaluation conducted on 14-06-2022 is submitted.~~
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 25-10-2022 specifying 300Kg levofloxacin dated by legacy pharma.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm
1.	Submit valid GMP certificate of API manufacturer.	
2.	Submit loan letter from Legacy Pharma since the API import documents of Legacy pharma has been submitted.	
3.	Submit complete stability study data including HPLC chromatograms, dissolution data and related analytical record since no such data has been submitted in module 3.	

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

146.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan**
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license dated 11th November 2021 for following sections: 1. Tablet (General) 2. Capsule (General) 3. Cream /ointment section (General) 4. Tablet (Hormone) 5. Dry Powder Suspension (General)
	Evidence of approval of manufacturing facility	Firm has been granted new license dated 11th November 2021 for following sections: 1. Tablet (General) 2. Capsule (General) 3. Cream /ointment section (General) 4. Tablet (Hormone) 5. Dry Powder Suspension (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. 4HU-N13-7R74: 01-03-2024
	Details of fee submitted	PKR 30,000/-: 03-11-2023
	The proposed proprietary name / brand name	**TAMSO 0.4mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Tamsulosin HCl (as SR Pellets).…0.4mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Alpha blocker
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Maxflow Capsule by CCL
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and

		its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Tamsolin Capsule of Getz. Firm has submitted CDP studies in 3 medium against Tamsolin Capsule of Getz
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.		
API Lot No.	TMS362		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 Capsule	1500 Capsule	1500 Capsule
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	08-05-2022	08-05-2022	08-05-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate on the basis of evaluation conducted on 14-06-2022 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 1Kg tamsulosin pellets dated 08-04-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Case No. 02 Registration applications of CTD cases

a. New cases

147.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Novamed Pharmaceuticals (Pvt) Ltd 28-Km, Ferozepur Road Lahore.**
	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals (Pvt) Ltd 28-Km, Ferozepur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 06-09-2021 based on evaluation conducted on 06-08-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 14-09-2021 specifying Tablet (General) Section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22884 dated 12-08-2022
	Details of fee submitted	PKR 75,000/- Dated 19-04-2022
	The proposed proprietary name / brand name	**XYSARTAN 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan medoxomil potassium eq to Azilsartan medoxomil…… 40mg
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Blocker
	Pharmaceutical form of applied drug	Yellow colored uncoated round shape core tablet plain from both sides
	Reference to Finished product specifications	Manufacturer's
	Proposed Pack size	10's, 20's, 30's, 28's, 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Edarbi Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Edarbi

		40mg Tablet Firm has submitted CDP results of their product against the innovator's product Edarbi Tablet 40mg in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India		
API Lot No.	21AK000004		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD/PR21-091/T1/S1	RD/PR21-091/T1/S2	RD/PR21-091/T1/S2
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	08-09-2021	08-09-2021	08-09-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Retention of License (No. G/25/1723) dated 29-01-2021 issued by Food and Drugs Control Administration Gujrat State India. The certificate specifies that the license to manufacture has been retained from 24/01/2021 to 23/01/2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications	

	and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
2.	The innovator's product recommends that the storage conditions for drug substance is from 2 to 8 degree and the same is also mentioned in section 3.2.S.7.1, however the stability study data of drug substance is conducted as per Zone IV-A conditions. Clarification is required in this regard.	
3.	As per the product review documents issued by USFDA, the drug product is practically insoluble in acidic and neutral aqueous solutions and is unstable in aqueous solution between pH 1 and pH 7. Data from other manufacturers as well as innovator's product shows very less drug release in 0.1 N HCl as well as 4.5 phosphate acetate buffer. Justify your results showing more than 60% results at 45 minutes in both of these medias. Clarification is required in this regard.	
4.	Justify the dissolution specifications NLT 75%(Q) without specifying any time.	
5.	Your standard solution concentration is 0.06mg/ml, while the limit of quantitation is 0.13417mg/ml. Justify how your standard solution can be quantified when its concentration is far below the limit of quantitation.	
6.	Submit readable copy of AD attested commercial invoice or clearance certificate	
7.	Submit valid copy of GMP certificate of the drug substance manufacturer.	

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

148.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Novamed Pharmaceuticals (Pvt) Ltd 28-Km, Ferozepur Road Lahore.**
	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals (Pvt) Ltd 28-Km, Ferozepur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 06-09-2021 based on evaluation conducted on 06-08-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 14-09-2021 specifying Tablet (General) Section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22883 dated 12-08-2022
	Details of fee submitted	PKR 75,000/- Dated 19-04-2022
	The proposed proprietary name / brand name	**XYSARTAN 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan medoxomil potassium eq to Azilsartan medoxomil…… 80mg
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Blocker
	Pharmaceutical form of applied drug	Yellow colored uncoated round shape core tablet plain from both sides
	Reference to Finished product specifications	Manufacturer's
	Proposed Pack size	10's, 20's, 30's, 28's, 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Edarbi Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Edarbi 80mg Tablet Firm has submitted CDP results of their product against the innovator's product Edarbi Tablet 80mg in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India		
API Lot No.	21AK000004		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD/PR21-084/T1/S1	RD/PR21-084/T1/S2	RD/PR21-084/T1/S2
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	08-09-2021	08-09-2021	08-09-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Retention of License (No. G/25/1723) dated 29-01-2021 issued by Food and Drugs Control Administration Gujrat State India. The certificate specifies that the license to manufacture has been retained from 24/01/2021 to 23/01/2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance	

	document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
2.	The innovator's product recommends that the storage conditions for drug substance is from 2 to 8 degree and the same is also mentioned in section 3.2.S.7.1, however the stability study data of drug substance is conducted as per Zone IV-A conditions. Clarification is required in this regard.	
3.	As per the product review documents issued by USFDA, the drug product is practically insoluble in acidic and neutral aqueous solutions and is unstable in aqueous solution between pH 1 and pH 7. Data from other manufacturers as well as innovator's product shows very less drug release in 0.1 N HCl as well as 4.5 phosphate acetate buffer. Justify your results showing more than 60% results at 45 minutes in both of these medias. Clarification is required in this regard.	
4.	Justify the dissolution specifications NLT 75%(Q) without specifying any time.	
5.	Your standard solution concentration is 0.06mg/ml, while the limit of quantitation is 0.13417mg/ml. Justify how your standard solution can be quantified when its concentration is far below the limit of quantitation.	
6.	Submit readable copy of AD attested commercial invoice or clearance certificate	
7.	Submit valid copy of GMP certificate of the drug substance manufacturer.	

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

149.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hudson Pharma Private Limited. Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Karachi Pakistan**
	Name, address of Manufacturing site.	M/s Hudson Pharma Private Limited. Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Karachi Pakistan
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued dated 04-04-2022 on the basis of inspection dated 07-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of approval of revised section dated 03-12-2018 specifying Eye / Ear & Nasal Drop (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23138: 16-08-2022
	Details of fee submitted	PKR 30,000/-: 21-07-2022
	The proposed proprietary name / brand name	**Teardrop Eye Drops 0.3% + 0.4% (15ml)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Polyethylene glycol 400……4mg Propylene glycol……3mg
	Pharmaceutical form of applied drug	Ophthalmic solution
	Pharmacotherapeutic Group of (API)	Eye Lubricant
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Systane Lubricant eye drops (Dailymed) USA Not available in Drugs@FDA database
	For generic drugs (me-too status)	2blink Eye Drops by Sante
	Name and address of API manufacturer.	**Propylene glycol:** Merck KGaA Frankfurter Str 250 64271 Darmstadt Germany. **Polyethylene Glycol:** Merck KGaA Frankfurter Str 250 64271 Darmstadt Germany.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug

		substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Propylene glycol:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Polyethylene Glycol:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against systane drops
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Propylene glycol:** Merck KGaA Frankfurter Str 250 64271 Darmstadt Germany. **Polyethylene Glycol:** Merck KGaA Frankfurter Str 250 64271 Darmstadt Germany.		
API Lot No.	**Propylene glycol:** K50526178 **Polyethylene Glycol:** K52394403		
Description of Pack (Container closure system)	LDPE plastic bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	SB-01	SB-02	SB-03
Batch Size	4.5 L	4.5 L	4.5 L
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	18-01-2022	18-01-2022	18-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to its previous inspection conducted for Bufen Injection 100mg. The inspection was conducted on 11-05-2018 and was considered by the Board in its 282nd meeting of RB.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Locally purchased
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail report of stability testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting, since you have claimed that the formulation is approved by MHRA with brand name "Systane" while no such approval is available in MHRA database. Moreover, you have also submitted weblink of dailymed database, while this product is not approved by USFDA and is not available in Drugs@FDA database. You are advised to provide documentary evidence that this product is approved as a pharmaceutical drug by USFDA or any other reference regulatory authority.	
2.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.", since you have only submitted copy of pharmacopoeial monograph instead of providing specifications and analytical method from drug substance manufacturer.	
3.	Submit evidence of testing facility and test reports for testing of diethylene glycol and ethylene glycol in both drug substances.	
4.	Provide verification studies of analytical method of both drug substance from drug product manufacturer	
5.	Justtify why the test and result for diethylene glycol and ethylene glycol is not specified in the batch analysis report of propylene glycol	
6.	The "systane" product available in dailymed database is preservative free, while your formulation contains two preservatives. Justification is required in this regard.	
7.	Specify how the sterility of the product is ensured since detailed mehod of manufacturing is not submitted in section 3.2.P.3.3.	
8.	Justify why assay test is not included in the specifications of drug product.	
9.	Justify how validation studies of the drug product has been performed since no assay method has been provided.	

10.	Submit GMP ccertificate of the drug substance manufacturer issued by relevant regulatory authority of Germany or submit Eudra GMP certificate, since the submitted GMP certificate is for pharmaceutical excipients.	
11.	Justify why both drug substances have been locally purchased however Registration Board has directed all manufacturers to import API only from licensed pharmaceutical manufacturers, while you have purchased API from Martin Dow.	

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

150.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hudson Pharma Private Limited. Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Karachi Pakistan**
	Name, address of Manufacturing site.	M/s Hudson Pharma Private Limited. Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Karachi Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued dated 04-04-2022 on the basis of inspection dated 07-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of approval of revised section dated 03-12-2018 specifying Eye / Ear & Nasal Drop (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23137: 16-08-2022
	Details of fee submitted	PKR 30,000/-: 21-07-2022
	The proposed proprietary name / brand name	**Teardrop Eye Drops 0.3% + 0.4% (30ml)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Polyethylene glycol 400……4mg Propylene glycol……3mg
	Pharmaceutical form of applied drug	Ophthalmic solution
	Pharmacotherapeutic Group of (API)	Eye Lubricant
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Systane Lubricant eye drops (Dailymed) USA Not available in Drugs@FDA database
	For generic drugs (me-too status)	2blink Eye Drops by Sante
	Name and address of API manufacturer.	**Propylene glycol:** Merck KGaA Frankfurter Str 250 64271 Darmstadt Germany. **Polyethylene Glycol:** Merck KGaA Frankfurter Str

		250 64271 Darmstadt Germany.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Propylene glycol:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Polyethylene Glycol:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against systane drops
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Propylene glycol:** Merck KGaA Frankfurter Str 250 64271 Darmstadt Germany. **Polyethylene Glycol:** Merck KGaA Frankfurter Str 250 64271 Darmstadt Germany.
API Lot No.	**Propylene glycol:** K50526178 **Polyethylene Glycol:** K52394403
Description of Pack (Container closure system)	LDPE plastic bottle
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	SB-01	SB-02	SB-03
Batch Size	6 L	6 L	4.5 L
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	18-01-2022	18-01-2022	18-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to its previous inspection conducted for Bufen Injection 100mg. The inspection was conducted on 11-05-2018 and was considered by the Board in its 282nd meeting of RB.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Locally purchased
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail report of stability testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting, since you have claimed that the formulation is approved by MHRA with brand name "Systane" while no such approval is available in MHRA database. Moreover, you have also submitted weblink of dailymed database, while this product is not approved by USFDA and is not available in Drugs@FDA database. You are advised to provide documentary evidence that this product is approved as a pharmaceutical drug by USFDA or any other reference regulatory authority.	
2.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.", since you have only submitted copy of pharmacopoeial monograph instead of providing	

	specifications and analytical method from drug substance manufacturer.	
3.	Submit evidence of testing facility and test reports for testing of diethylene glycol and ethylene glycol in both drug substances.	
4.	Provide verification studies of analytical method of both drug substance from drug product manufacturer	
5.	Justtify why the test and result for diethylene glycol and ethylene glycol is not specified in the batch analysis report of propylene glycol	
6.	The "systane" product available in dailymed database is preservative free, while your formulation contains two preservatives. Justification is required in this regard.	
7.	Specify how the sterility of the product is ensured since detailed mehod of manufacturing is not submitted in section 3.2.P.3.3.	
8.	Justify why assay test is not included in the specifications of drug product.	
9.	Justify how validation studies of the drug product has been performed since no assay method has been provided.	
10.	Submit GMP ccertificate of the drug substance manufacturer issued by relevant regulatory authority of Germany or submit Eudra GMP certificate, since the submitted GMP certificate is for pharmaceutical excipients.	
11.	Justify why both drug substances have been locally purchased however Registration Board has directed all manufacturers to import API only from licensed pharmaceutical manufacturers, while you have purchased API from Martin Dow.	

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

151.	Name, address of Applicant / Marketing Authorization Holder	**M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-11-2021 specifying Tablet (general) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 23835 dated 23-08-2022
	Details of fee submitted	PKR 30,000/- Dated 25-07-2022
	The proposed proprietary name / brand name	**PENTAL 75mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tapentadol as HCl…….75mg
	Pharmaceutical form of applied drug	Film Coated Tablet
	Pharmacotherapeutic Group of (API)	Analgesic
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nucynta TAblet (**USFDA** Approved)
	For generic drugs (me-too status)	Tapento Tablet by Sami
	Name and address of API manufacturer.	Arene Life Sciences Private Limited (Unit-1) Plot No. 48, 49 & 50, 209, 210 & 211 Phase-II, IDA, Pashamylaram Sangareddy Dist, Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Tapento IR Tablet of Sami Firm has submitted results of CDP studies for their

		product against Tapento IR Tablet of Sami
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA

Manufacturer of API	Arene Life Sciences Private Limited (Unit-1) Plot No. 48, 49 & 50, 209, 210 & 211 Phase-II, IDA, Pashamylaram Sangareddy Dist, Telangana, India.		
API Lot No.	TPD01190001/U-1		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	29-11-2021	29-11-2021	29-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DCA Government of Telanganaa India issued on 09-10-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Submitted
2.	Submit verification studies of analytical method of drug substance performed by drug product manufacturer.	Not submitted

3.	Submit stability study data of API as per zone IV-A conditions.	The submitted stability data is as per zone II instead of zone IV-A
4.	Specify details including the expiry date and manufacturer of the product against which pharmaceutical equivalence studies and CDP studies are conducted	Submitted
5.	Submit documents confirming import of API	Not submitted
6.	Submit stability studies as per 6 points checklist specified in the CTD guidance document.	Not submitted

Decision: Deferred for following submissions:

- **Verification studies of analytical method of drug substance performed by drug product manufacturer.**
- **Stability study data of API as per zone IV-A conditions.**
- **Documents for the procurement of API with approval from DRAP (in case of import).**
- **Submission of stability study data in section 3.2.P.8.3 in proper sequence and as per the checklist specified in CTD guidance document.**

152.	Name, address of Applicant / Marketing Authorization Holder	**M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-11-2021 specifying Tablet (general) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 24207 dated 26-08-2022
	Details of fee submitted	PKR 30,000/- Dated 22-08-2022
	The proposed proprietary name / brand name	**CABER 0.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Cabergoline…0.5mg
	Pharmaceutical form of applied drug	Uncoated Tablet
	Pharmacotherapeutic Group of (API)	Dopamine Receptor Agonists
	Reference to Finished product specifications	USP
	Proposed Pack size	8’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dostinex Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	Not submitted

	Name and address of API manufacturer.	Teva Pharmaceutical Industries Ltd. 5 Basel Street, P.O. Box 3190 Petach Tikva 4951033, Israel
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Dostinex Tablet Firm has submitted results of CDP studies for their product against Dostinex Tablet
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA	
Manufacturer of API	Teva Pharmaceutical Industries Ltd. 5 Basel Street, P.O. Box 3190 Petach Tikva 4951033, Israel
API Lot No.	70235000421
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months)

	Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	30-11-2021	30-11-2021	30-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

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

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

153.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Pharmevo Private Limited Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of the firm based on inspection dated 23-06-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of sections dated 21-02-2018. The letter specifies Tablet (General) section Revised.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25239: 06-09-2022
	Details of fee submitted	PKR 30,000/- : 11-08-2022
	The proposed proprietary name / brand name	**KLEVRA 750mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Levetiracetam…750mg
	Pharmaceutical form of applied drug	Antiepileptic
	Pharmacotherapeutic Group of (API)	Uncoated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	7's, 10's, 14's, 20's, 21's, 28's, 30's, 56's, 84's, 100's, 122's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Keppra Tablet (**MHRA** Approved)
	For generic drugs (me-too status)	Lerace Tablet by Hilton Pharma
	Name and address of API manufacturer.	Venkata Narayana Active Ingredients Private Limited Sy. No. 69, Chandrapadiya Village, Vinjamur Mandal, Nellore District-524228 Andhra Pradesh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form,

		manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-B conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Lerace Tablet of Hilton Pharma Firm has submitted CDP results of their product against Lerace Tablet of Hilton Pharma
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Venkata Narayana Active Ingredients Private Limited Sy. No. 69, Chandrapadiya Village, Vinjamur Mandal, Nellore District-524228 Andhra Pradesh, India		
API Lot No.	LT0280420		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21PD-3584-13-T	21PD-3595-14-T	21PD-3596-15-T
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	01-04-2021	01-04-2021	01-04-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Product specific inspection for Empagin XR Tablet has been conducted on 05-12-2019 and the case was approved in 293rd meeting.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Drug Control Administration Government of Andhra Pradesh India on 12-2021.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 14-05-2020 specifying 100Kg Levetiracetam. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

154.	Name, address of Applicant / Marketing Authorization Holder	**M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-11-2021 specifying Tablet (general) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 25814 dated 13-09-2022
	Details of fee submitted	PKR 30,000/- Dated 12-09-2022
	The proposed proprietary name / brand name	**AFTANIL 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rebamipide…100mg
	Pharmaceutical form of applied drug	Film Coated Tablet
	Pharmacotherapeutic Group of (API)	Anti ulcer
	Reference to Finished product specifications	JP
	Proposed Pack size	100’s

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Mucosta Tablet (**PMDA** Japan Approved)
	For generic drugs (me-too status)	Mucosta Tablet by Otsuka
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co., Ltd Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province, P.R.China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-B conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Mucosta Tablet of Otsuka Firm has submitted results of CDP studies for their product against Mucosta Tablet of Otsuka
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA	
Manufacturer of API	Jiangxi Synergy Pharmaceutical Co., Ltd Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province, P.R.China
API Lot No.	05-20210624C
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	01-04-2022	01-04-2022	01-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Translated Copy of DML certificate issued by CFDA China valid till 26-11-2025 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of me-too status since fee of generic application is submitted.	Mucosta Tablet by Otsuka
2.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has only submitted specifications and analytical method of drug substance from product manufacturer, however the specifications of drug substance manufacturer are not submitted.
3.	Specify details including the expiry date and manufacturer of the product against which pharmaceutical equivalence studies and CDP studies are conducted	Not submitted
4.	Submit documents confirming import of API	Not submitted
5.	Submit stability studies as per 6 points checklist specified in the CTD guidance document.	Not submitted

Decision: Deferred for following submissions:

- **Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer.**

- **Details including the expiry date and manufacturer of the product against which pharmaceutical equivalence studies and CDP studies are conducted.**
- **Documents for the procurement of API with approval from DRAP (in case of import).**
- **Submission of stability study data in section 3.2.P.8.3 in proper sequence and as per the checklist specified in CTD guidance document.**

155.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aulton Pharmaceuticals Plot # 84/1, Block A, Phase 5, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Aulton Pharmaceuticals Plot # 84/1, Block A, Phase 5, Industrial Estate, Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of the firm based on inspection dated 11-12-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License (DML No. 000828) dated 25-11-2021. The letter specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26942: 23-09-2022
	Details of fee submitted	PKR 75,000/- : 14-09-2022
	The proposed proprietary name / brand name	**ZILSART 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Azilsartan Medoxomil Potassium Eq. to Azilsartan Medoxomil…40mg
	Pharmaceutical form of applied drug	Angiotensin Receptor Blocker
	Pharmacotherapeutic Group of (API)	Uncoated tablet
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Edarbi Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure

		system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Edarbi Tablet Firm has submitted CDP results of their product against the innovator's product Edarbi Tablet in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India		
API Lot No.	19AK00006		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T013	T014	T015
Batch Size	1200 Tablet	1200 Tablet	1200 Tablet
Manufacturing Date	04-2021	04-2021	04-2021

Date of Initiation		04-2021	04-2021	04-2021
No. of Batches		03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Product specific inspection for aultadex capsule has been conducted on 12th February 2019 and the case was approved in 288th meeting.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Retention of License (No. G/25/1723) dated 29-01-2021 issued by Food and Drugs Control Administration Gujrat State India. The certificate specifies that the license to manufacture has been retained from 24/01/2021 to 23/01/2026.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 03-07-2019 specifying 0.540Kg Azilsartan medoxomil potassium. The invoice is cleared by AD (I&E) DRAP.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
Evaluation by PEC:				
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**				
156.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aulton Pharmaceuticals Plot # 84/1, Block A, Phase 5, Industrial Estate, Hattar, Pakistan**		
	Name, address of Manufacturing site.	M/s Aulton Pharmaceuticals Plot # 84/1, Block A, Phase 5, Industrial Estate, Hattar, Pakistan		
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)		
	GMP status of the firm	Firm has submitted copy of GMP certificate of the firm based on inspection dated 11-12-2020.		
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License (DML No. 000828) dated 25-11-2021. The letter specifies Tablet (General) section.		
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)		
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale		

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27276: 26-09-2022
	Details of fee submitted	PKR 75,000/- : 20-09-2022
	The proposed proprietary name / brand name	**ZILSART 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Azilsartan Medoxomil Potassium Eq. to Azilsartan Medoxomil…80mg
	Pharmaceutical form of applied drug	Angiotensin Receptor Blocker
	Pharmacotherapeutic Group of (API)	Uncoated tablet
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Edarbi Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials,

		container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Edarbi Tablet Firm has submitted CDP results of their product against the innovator's product Edarbi Tablet in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India		
API Lot No.	19AK00006		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T016	T017	T018
Batch Size	1200 Tablet	1200 Tablet	1200 Tablet
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	04-2021	04-2021	04-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Product specific inspection for aultadex capsule has been conducted on 12th February 2019 and the case was approved in 288th meeting.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Retention of License (No. G/25/1723) dated 29-01-2021 issued by Food and Drugs Control Administration Gujrat State India. The certificate specifies that the license to manufacture has been retained from 24/01/2021 to 23/01/2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 03-07-2019 specifying 0.540Kg Azilsartan medoxomil potassium. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

157.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Pharmevo Private Limited Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of the firm based on inspection dated 23-06-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of sections dated 21-02-2018. The letter specifies Tablet (General) section Revised.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27126: 26-09-2022
	Details of fee submitted	PKR 30,000/- : 05-08-2022
	The proposed proprietary name / brand name	**ZILSAR 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Azilsartan Medoxomil (as Potassium)…40mg
	Pharmaceutical form of applied drug	Angiotensin Receptor Blocker
	Pharmacotherapeutic Group of (API)	Uncoated tablet
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	7's, 10's, 14's, 20's, 21's, 28's, 30's, 56's, 84's, 100's, 122's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Edarbi Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	Aziltec Tablet 40mg by Nabiqasim
	Name and address of API manufacturer.	AMI Lifesciences Pvt Ltd. Block No.82/B, ECP Road, AT & Post. Karakhadi-391 450 Taluka-Padra, District-Vadodara Gujarat, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Edarbi Tablet Firm has submitted CDP results of their product against the innovator's product Edarbi Tablet in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	AMI Lifesciences Pvt Ltd. Block No.82/B, ECP Road, AT & Post. Karakhadi-391 450 Taluka-Padra, District-Vadodara Gujarat, INDIA		
API Lot No.	AZP/50150820		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22PD-0085-34-SB	22PD-0086-35-SB	22PD-0087-36-SB

Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	03-03-2022	03-03-2022	03-03-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Product specific inspection for Empagin XR Tablet has been conducted on 05-12-2019 and the case was approved in 293rd meeting.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Food and Drug Control Administration Gujrat State India valid till 17-04-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 01-12-2020 specifying 1.6Kg Azilsartan medoxomil potassium. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

158.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Searle Pakistan Limited. C-14, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s The Searle Company Limited. F-319, S.I.T.E, Karachi, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted cGMP certificate issued on the basis of inspection conducted on 08-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License dated 26-10-2020 specifying Soft gelatin capsule (Hormone) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27745: 30-09-2022
	Details of fee submitted	PKR 30,000/-: 30-03-2022
	The proposed proprietary name / brand name	**OGESTRON 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Progesterone (Micronized)…100mg
	Pharmaceutical form of applied drug	Soft gelatin capsule
	Pharmacotherapeutic Group of (API)	Progestins
	Reference to Finished product specifications	As per innovator's product
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Prometrium 100 mg soft capsules for oral and vaginal use in Italy
	For generic drugs (me-too status)	U-Progest capsule by Aspin Pharma
	Name and address of API manufacturer.	Hubei Gedian Humanwell Pharmaceutical co. Ltd. E-Zhou City, Hubei Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against U-Progest 100mg Capsule of Searle Firm has not submitted Comparative Dissolution Profile studies and submitted justification that as per their understanding CDP is not required
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Hubei Gedian Humanwell Pharmaceutical co. Ltd. E-Zhou City, Hubei Province China.		
API Lot No.	HTT190904		
Description of Pack (Container closure system)	Alu-PVC PVDC Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 35% RH Accelerated: 40°C ± 2°C / 25% RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Real Time: 0, 3, 6 (Months) Accelerated: 0, 3, 6 (Months)		
Batch No.	039S02	040S02	041S02
Batch Size	75000 Capsule	75000 Capsule	75000 Capsule
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	03-2020	03-2020	03-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Written confirmation for active substances exported to EU valid till 26-10-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Commercial invoice specifying 225kg progesterone micronized cleared dated 03-12-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record of stability testing of 3 batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted by the firm
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted by the firm

Evaluation by PEC:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

159.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Searle Pakistan Limited. C-14, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s The Searle Company Limited. F-319, S.I.T.E, Karachi, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted cGMP certificate issued on the basis of inspection conducted on 08-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License dated 26-10-2020 specifying Soft gelatin capsule (Hormone) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27746: 30-09-2022
	Details of fee submitted	PKR 30,000/-: 30-03-2022
	The proposed proprietary name / brand name	**OGESTRON 200mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Progesterone (Micronized)…..200mg
	Pharmaceutical form of applied drug	Soft gelatin capsule
	Pharmacotherapeutic Group of (API)	Progestins
	Reference to Finished product specifications	As per innovator's product
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Prometrium 200 mg soft capsules for oral and vaginal use in Italy
	For generic drugs (me-too status)	U-Progest capsule by Aspin Pharma
	Name and address of API manufacturer.	Hubei Gedian Humanwell Pharmaceutical co. Ltd. E-Zhou City, Hubei Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against U-Progest 200mg Capsule of Searle Firm has not submitted Comparative Dissolution Profile studies and submitted justification that as per their understanding CDP is not required
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Hubei Gedian Humanwell Pharmaceutical co. Ltd. E-Zhou City, Hubei Province China.		
API Lot No.	HTT171101		
Description of Pack (Container closure system)	Alu-PVC PVDC Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 35% RH Accelerated: 40°C ± 2°C / 25% RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Real Time: 0, 3, 6 (Months) Accelerated: 0, 3, 6 (Months)		
Batch No.	B1194	B1195	B1196
Batch Size	50000 Capsule	50000 Capsule	50000 Capsule
Manufacturing Date	04-2018	04-2018	04-2018
Date of Initiation	05-2018	05-2018	05-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Written confirmation for active substances exported to EU valid till 26-10-2023

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Commercial invoice specifying 50kg progesterone cleared dated 02-01-2018.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record of stability testing of 3 batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted by the firm
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted by the firm
Evaluation by PEC:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

160.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 14-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 07-06-2022 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27738: 30-09-2022
	Details of fee submitted	PKR 75,000/-: 28-09-2022
	The proposed proprietary name / brand name	**ELGOZON 150mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Elagolix Sodium eq to Elagolix ……150mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Gonadotropin-releasing hormone (GnRH) receptor antagonist
	Clinical Indication	ORILISSA is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the

		management of moderate to severe pain associated with endometriosis
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Orilissa Tablet (USFDA Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Biophore India Pharmaceuticals Pvt Ltd Plot no. 80-A, Road no. 5, JN Pharma City, Parawada, E Bonangi Visakhapatnam-531021, Andhra Pradesh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Orilissa tablet Firm has submitted results of CDP for their product against Orilissa tablet
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Biophore India Pharmaceuticals Pvt Ltd Plot no. 80-A, Road no. 5, JN Pharma City, Parawada, E Bonangi Visakhapatnam-531021, Andhra Pradesh, India		
API Lot No.	6024/3/001/21		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ELXL-001	ELXL-002	ELXL-003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	18-04-2022	18-04-2022	19-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their last product specific inspection conducted for "Empazon 10mg & 25mg Tablet", which was conducted on 1st June, 2021, and was presented in 307th meeting of Registration Board. The report confirms following points: The HPLC software is 21CFR Compliant. Firm has demonstrated Audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Andhra Pradesh dated 06-04-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 13-12-2021. The invoice specifies 2kg Elagolix.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

161.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 14-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 07-06-2022 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27739: 30-09-2022
	Details of fee submitted	PKR 75,000/-: 28-09-2022
	The proposed proprietary name / brand name	**ELGOZON 200mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Elagolix Sodium eq to Elagolix ……200mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Gonadotropin-releasing hormone (GnRH) receptor antagonist
	Clinical Indication	ORILISSA is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Orilissa Tablet (USFDA Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Biophore India Pharmaceuticals Pvt Ltd Plot no. 80-A, Road no. 5, JN Pharma City, Parawada, E Bonangi Visakhapatnam-531021, Andhra Pradesh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Orilissa tablet Firm has submitted results of CDP for their product against Orilissa tablet
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Biophore India Pharmaceuticals Pvt Ltd Plot no. 80-A, Road no. 5, JN Pharma City, Parawada, E Bonangi Visakhapatnam-531021, Andhra Pradesh, India		
API Lot No.	6024/3/001/21		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ELXH-001	ELXH-002	ELXH-003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	22-04-2022	18-04-2022	23-04-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their last product specific inspection conducted for "Empazon 10mg & 25mg Tablet", which was conducted on 1st June, 2021, and was presented in 307th meeting of Registration Board. The report confirms following points: The HPLC software is 21CFR Compliant. Firm has demonstrated Audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Andhra Pradesh dated 06-04-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 13-12-2021. The invoice specifies 2kg Elagolix.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC[3]:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

162.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 14-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 07-06-2022 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27409: 30-09-2022
	Details of fee submitted	PKR 75,000/-: 26-09-2022

	The proposed proprietary name / brand name	**ASPIRO Tablet 81/40mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Aspirin…81mg Omeprazole…40mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	PPI along with non selective COX inhibitor
	Clinical Indication	YOSPRALA, a combination of aspirin and omeprazole, is indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers.
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	YOSPRALA Tablet (USFDA Approved but discontinued, however a generic product is also granted tentative approval)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	**Aspirin:** JQC (Huayin Pharmaceutical Co, Limited. Yuquan Road, Huayin City, Shanxi Province, P.R of China. **Omeprazole:** Metrochem API Private Limited Plot No. 62/C/6, Pipe Line Road Phase I, IDA Jeedimetla Hyderabad Telangana State India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Aspirin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months. **Omeprazole:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The

		accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Yosprala tablet Firm has submitted results of CDP for their product against Yosprala tablet
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Aspirin:** JQC (Huayin Pharmaceutical Co, Limited. Yuquan Road, Huayin City, Shanxi Province, P.R Of China. **Omeprazole:** Metrochem API Private Limited Plot No. 62/C/6, Pipe Line Road Phase I, IDA Jeedimetla Hyderabad Telangana State India.		
API Lot No.	**Aspirin:** A2108011 **Omeprazole:** OMP/2101012		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	AOL-001	AOL-002	
Batch Size	5000 Tablet	5000 Tablet	
Manufacturing Date	12-2021	12-2021	
Date of Initiation	12-2021	12-2021	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their last product specific inspection conducted for "Empazon 10mg & 25mg Tablet", which was conducted on 1st June, 2021, and was presented in 307th meeting of Registration Board. The report confirms following points: The HPLC software is 21CFR Compliant. Firm has demonstrated Audit trail reports of testing.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Aspirin:** Firm has submitted copy of DML issued by CFDA China valid till 16-12-2025. **Omeprazole:** Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Aspirin:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-10-2021. The invoice specifies 2kg Elagolix. **Omeprazole:** Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Tentative Approval (USFDA)

If a generic drug product is ready for approval before the expiration of any patents or exclusivities accorded to the reference listed drug product, FDA issues a tentative approval letter to the applicant. The tentative approval letter details the circumstances associated with the tentative approval. FDA delays final approval of the generic drug product until all patent or exclusivity issues have been resolved. A tentative approval does not allow the applicant to market the generic drug product.

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of full fee.	Firm has submitted revised label label as under: Each Film Coated Tablet Contains: Aspirin (delayed release)…81mg Omeprazole (immediate release)…40mg
2.	Submit evidence of approval of applied formulation in reference regulatory authorities, since the submitted reference of USFDA have been discontinued without specifying the reason for discontinuation.	Due to commercial reason YOSPRALA has been discontinued from the market. Moreover a generic version of this product has also received tentative approval from USFDA as well.
3.	Submit real time stability study data of 3 batches of aspirin conducted as per zone IV-A conditions.	Submitted
4.	Justify the use of working standard of omeprazole from Surge Laboratories, since the API supplier for omeprazole is Metrochem India.	Omeprazole API was taken as loan from Surge laboratories therefore the same working standard was also used.
5.	Provide complete method of manufacturing since no step specifying the manufacturing of omeprazole layer is provided.	Detailed method is submitted.
6.	Justify the process validation in which the step of manufacturing of omeprazole layer is not include although being the most critical step.	Complete process validation is submitted.
7.	Submit analytical method for testing of the drug product	Analytical method is submitted.

8.	Justify the drug product specification which do not contain any time point for dissolution test.	Updated analytical method has been submitted.
9.	Submit valid GMP certificate of the manufacturer of omeprazole, since the submitted GMP is not valid.	Submitted
10.	Submit document for import of omeprazole since the submitted invoice is of Surge Laboratories.	Submitted

Decision: Approved.

- **Manufacturer will submit the compliance report in accordance to the decision of authority regarding products not having RRA status, though the instant product posses the tentative approval by USA.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

163.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 14-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 07-06-2022 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27736: 30-09-2022
	Details of fee submitted	PKR 75,000/-: 26-09-2022
	The proposed proprietary name / brand name	**ASPIRO Tablet 325/40mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Aspirin…325mg Omeprazole…40mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	PPI along with non selective COX inhibitor
	Clinical Indication	YOSPRALA, a combination of aspirin and omeprazole, is indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers.
	Reference to Finished product specifications	Innovator's specs

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	YOSPRALA Tablet (USFDA Approved but discontinued, however a generic product is also granted tentative approval)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	**Aspirin:** JQC (Huayin Pharmaceutical Co, Limited. Yuquan Road, Huayin City, Shanxi Province, P.R of China. **Omeprazole:** Metrochem API Private Limited Plot No. 62/C/6, Pipe Line Road Phase I, IDA Jeedimetla Hyderabad Telangana State India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Aspirin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months. **Omeprazole:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Yosprala tablet Firm has submitted results of CDP for their product against Yosprala tablet
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Aspirin:** JQC (Huayin Pharmaceutical Co, Limited. Yuquan Road, Huayin City, Shanxi Province, P.R Of China. **Omeprazole:** Metrochem API Private Limited Plot No. 62/C/6, Pipe Line Road Phase I, IDA Jeedimetla Hyderabad Telangana State India.		
API Lot No.	**Aspirin:** A2108011 **Omeprazole:** OMP/2101012		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	AOH-001	AOH-002	
Batch Size	5000 Tablet	5000 Tablet	
Manufacturing Date	12-2021	12-2021	
Date of Initiation	12-2021	12-2021	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their last product specific inspection conducted for "Empazon 10mg & 25mg Tablet", which was conducted on 1st June, 2021, and was presented in 307th meeting of Registration Board. The report confirms following points: The HPLC software is 21CFR Compliant. Firm has demonstrated Audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Aspirin:** Firm has submitted copy of DML issued by CFDA China valid till 16-12-2025. **Omeprazole:** Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Aspirin:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-10-2021. The invoice specifies 2kg Elagolix. **Omeprazole:** Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Tentative Approval (USFDA)
If a generic drug product is ready for approval before the expiration of any patents or exclusivities accorded to the reference listed drug product, FDA issues a tentative approval letter to the applicant. The tentative approval letter details the circumstances associated with the tentative approval. FDA delays final approval of the generic drug product until all patent or exclusivity issues have been resolved. A tentative approval does not allow the applicant to market the generic drug product.

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of full fee.	Firm has submitted revised label label as under: Each Film Coated Tablet Contains: Aspirin (delayed release)…325mg Omeprazole (immediate release)…40mg
2.	Submit evidence of approval of applied formulation in reference regulatory authorities, since the submitted reference of USFDA have been discontinued without specifying the reason for discontinuation.	Due to commercial reason YOSPRALA has been discontinued from the market. Moreover a generic version of this product has also received tentative approval from USFDA as well.
3.	Submit real time stability study data of 3 batches of aspirin conducted as per zone IV-A conditions.	Submitted
4.	Justify the use of working standard of omeprazole from Surge Laboratories, since the API supplier for omeprazole is Metrochem India.	Omeprazole API was taken as loan from Surge laboratories therefore the same working standard was also used.
5.	Provide complete method of manufacturing since no step specifying the manufacturing of omeprazole layer is provided.	Detailed method is submitted.
6.	Justify the process validation in which the step of manufacturing of omeprazole layer is not include although being the most critical step.	Complete process validation is submitted.
7.	Submit analytical method for testing of the drug product	Analytical method is submitted.
8.	Justify the drug product specification which do not contain any time point for dissolution test.	Updated analytical method has been submitted.
9.	Submit valid GMP certificate of the manufacturer of omeprazole, since the submitted GMP is not valid.	Submitted
10.	Submit document for import of omeprazole since the submitted invoice is of Surge Laboratories.	Submitted

Decision: Approved.

- **Manufacturer will submit the compliance report in accordance to the decision of authority regarding products not having RRA status, though the instant product posses the tentative approval by USA.**

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Agenda of Evaluator PEC-IV

Case no. 01 Registration applications for local manufacturing of (Human) drugs

a. New cases

164.	Name, address of Applicant / Marketing Authorization Holder	M/s ICI Pakistan Limited. 32/2A Phase III, Industrial Estate Hattar Pakistan
	Name, address of Manufacturing site.	M/s ICI Pakistan Limited. 32/2A Phase III, Industrial Estate Hattar Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 07-06-2022 based on inspection conducted on 06-06-2022 and valid for 2 years..
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 16-06-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23139 dated 16-08-2022
	Details of fee submitted	PKR 30,000/- Deposit Slip# 748992774
	The proposed proprietary name / brand name	**Lumont 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Chewable Tablet Contains: Montelukast as Sodium……4mg
	Pharmacotherapeutic Group of (API)	Light green color, round shaped biconvex chewable tablets.
	Pharmaceutical form of applied drug	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SINGULAIR 4mg Chewable tablet, by Organon of USFDA Approved.
	For generic drugs (me-too status)	Myteka 4mg Chewable Tablet by Hilton Pharma (Pvt) Ltd
	Name and address of API manufacturer.	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. **Address:** No. 15, Donghai 5th Avenue, Zhejiang Provincial chemical and medical Raw Materials

		Base Linhai Zone, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5% for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Myteka 4mg Chewable Tablet by Hilton Pharma (Pvt) Ltd performing quality tests (Identification, Physical appearance, Uniformity of weight, Dissolution, Assay). CDP has been performed against the ' Myteka 4mg Chewable Tablet by Hilton Pharma (Pvt) Ltd in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA	
Manufacturer of API	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. **Address:** No. 15, Donghai 5th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
API Lot No.	11001-210513
Description of Pack (Container closure system)	Alu Alu foil
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST1A126	ST1A127	ST1A128
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	08-02-2022	08-02-2022	08-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML No# Zhejiang 20050431 issued by China food and Drug Control administration dated: 17-06-2020 and valid until 16.06.2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 3, form 6, form 7 and Commercial Invoice # TY121675 dated: 29-07-2021 specifying 1Kg of Montelukast Sodium batch # 11001-210513.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Submitted
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Submitted
3.	3.2.S.4.1	Drug substance specifications by Drug product manufacturer specified test of sodium while specification claimed are USP . Clarify.	Drug substance specifications by drug product manufacturer specified test of sodium is for identification only, Drug substance manufacturer also mentioned in specification, identification of sodium is also mentioned in USP monograph. Hence

			product manufacturer drug substance method is completely harmonized with USP method. Method of product manufacturer of dug substance and USP method has been attached
4.	3.2.P.8	• Submit commercial invoice attested by DRAP. • Batch No of drug substance mentioned in stability studies is different than Batch No mentioned on submitted COA by drug product manufacturer. • Clarification is required either the eluted main peak depicted in the chromatogram sheets of sensitivity solution and standard solution was of montelukast or montelukast dicyclohexylamine, since the specified name of main peak is montelukast in all the chromatogram sheets. • Submit 6th month stability studies data of drug product since you have submitted the data of only 3 months. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Form 6 issued by DRAP along-with invoice and Airway bill attached. • Batch number of drug substance mentioned in stability studies is a typographic error, however submitted COA by firm Batch no. is correct. • The eluted main peak depicted in the chromatogram sheets of sensitivity and standard solutions is of Montelukast dicylohexylamine. The relevant chromatogram of Primary USP reference standard of Montelukast dicyclohexylamine with identified peak is attached along-with COA • 6th month stability data has been submitted on 4-10-2022. However duplicate stability data. • Submitted.

Fee for change of title from M/s ICI Pakistan Limited to M/s Lucky Core Industries Limited, Haripur submitted Rs:30000/- Deposit slip# 11644965

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

165.	Name, address of Applicant / Marketing Authorization Holder	M/s ICI Pakistan Limited. 32/2A Phase III, Industrial Estate Hattar Pakistan
	Name, address of Manufacturing site.	M/s ICI Pakistan Limited. 32/2A Phase III, Industrial Estate Hattar Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 07-06-2022 based on inspection conducted on 06-06-2022 and valid for 2 years..
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 16-06-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23140 dated 16-08-2022
	Details of fee submitted	PKR 30,000/- Deposit Slip# 62259464703
	The proposed proprietary name / brand name	**Lumont 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Chewable Tablet Contains: Montelukast as Sodium……5mg
	Pharmacotherapeutic Group of (API)	Light green color, round shaped biconvex chewable tablets.
	Pharmaceutical form of applied drug	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SINGULAIR 5mg Chewable tablet, by Organon of USFDA Approved.
	For generic drugs (me-too status)	Myteka 5mg Chewable Tablet by Hilton Pharma (Pvt) Ltd
	Name and address of API manufacturer.	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. **Address:** No. 15, Donghai 5th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5% for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch

		analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Myteka 5mg Chewable Tablet by Hilton Pharma (Pvt) Ltd performing quality tests (Identification, Physical appearance, Uniformity of weight, Dissolution, Assay). CDP has been performed against the ‘ Myteka 5mg Chewable Tablet by Hilton Pharma (Pvt) Ltd in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. **Address:** No. 15, Donghai 5th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.		
API Lot No.	11001-210513		
Description of Pack (Container closure system)	Alu Alu foil		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST1A129	ST1A130	ST1A131
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	08-02-2022	08-02-2022	08-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML No# Zhejiang 20050431 issued by China food and Drug Control administration dated: 17-06-2020 and valid until 16.06.2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 3, form 6, form 7 and Commercial Invoice # TY121675 dated: 29-07-2021 specifying 1Kg of Montelukast Sodium batch # 11001-210513.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Submitted
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Submitted
3.	3.2.S.4.1	Drug substance specifications by Drug product manufacturer specified test of sodium while specification claimed are USP . Clarify.	Drug substance specifications by drug product manufacturer specified test of sodium is for identification only, Drug substance manufacturer also mentioned in specification, identification of sodium is also mentioned in USP monograph. Hence product manufacturer drug substance method is completely harmonized with USP method. Method of product manufacturer of dug substance and USP method has been attached
4.	3.2.P.8	• Submit commercial invoice attested by DRAP. • Batch No of drug substance mentioned in stability studies is different than Batch No mentioned on submitted COA by drug product manufacturer. • Clarification is required either the eluted main peak depicted in the chromatogram sheets of sensitivity solution and standard solution was of montelukast or montelukast dicyclohexylamine, since the specified name of main peak is montelukast in all the chromatogram sheets. • Submit 6th month stability studies data of drug product since you have submitted the data of only 3 months. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Form 6 issued by DRAP along-with invoice and Airway bill attached. • Batch number of drug substance mentioned in stability studies is a typographic error, however submitted COA by firm Batch no. is correct. • The eluted main peak depicted in the chromatogram sheets of sensitivity and standard solutions is of Montelukast dicylohexylamine. The relevant chromatogram of Primary USP reference standard of Montelukast dicyclohexylamine with identified peak is attached along-with COA • 6th month stability data has been submitted on 4-10-2022. However duplicate stability data. • Submitted.

Fee for change of title from M/s ICI Pakistan Limited to M/s Lucky Core Industries Limited, Haripur submitted Rs:30000/- Deposit slip# 22661152591		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
166.	Name, address of Applicant / Marketing Authorization Holder	M/s ICI Pakistan Limited. 32/2A Phase III, Industrial Estate Hattar Pakistan
	Name, address of Manufacturing site.	M/s ICI Pakistan Limited. 32/2A Phase III, Industrial Estate Hattar Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 07-06-2022 based on inspection conducted on 06-06-2022 and valid for 2 years..
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 16-06-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23141 dated 16-08-2022
	Details of fee submitted	PKR 30,000/- Deposit Slip# 22797145
	The proposed proprietary name / brand name	**Lumont 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Montelukast as sodium…….10mg
	Pharmacotherapeutic Group of (API)	Green color, round shaped biconvex film coated tablets.
	Pharmaceutical form of applied drug	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SINGULAIR 10mg tablet, by Organon of USFDA Approved.
	For generic drugs (me-too status)	Myteka 10mg Chewable Tablet by Hilton Pharma (Pvt) Ltd
	Name and address of API manufacturer.	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. **Address:** No. 15, Donghai 5th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5% for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Myteka 10mg Tablet by Hilton Pharma (Pvt) Ltd performing quality tests (Identification, Physical appearance, Uniformity of weight, Dissolution, Assay). CDP has been performed against the ' Myteka 10mg Tablet by Hilton Pharma (Pvt) Ltd in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. **Address:** No. 15, Donghai 5th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.		
API Lot No.	11001-210513		
Description of Pack (Container closure system)	Alu Alu foil		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST1A135	ST1A136	ST1A137

Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	08-02-2022	08-02-2022	08-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML No# Zhejiang 20050431 issued by China food and Drug Control administration dated: 17-06-2020 and valid until 16.06.2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 3, form 6, form 7 and Commercial Invoice # TY121675 dated: 29-07-2021 specifying 1Kg of Montelukast Sodium batch # 11001-210513.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Submitted
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Submitted
3.	3.2.S.4.1	Drug substance specifications by Drug product manufacturer specified test of sodium while specification claimed are USP . Clarify.	Drug substance specifications by drug product manufacturer specified test of sodium is for identification only, Drug substance manufacturer also mentioned in specification, identification of sodium is also mentioned in USP monograph. Hence product manufacturer drug substance method is completely harmonized with USP method. Method of product manufacturer of dug substance and USP method has been attached
4.	3.2.P.8	• Submit commercial invoice attested by DRAP. • Batch No of drug substance mentioned in stability studies is different than Batch No mentioned	• Form 6 issued by DRAP along-with invoice and Airway bill attached. • Batch number of drug substance mentioned in stability studies is a typographic error, however

		on submitted COA by drug product manufacturer. • Clarification is required either the eluted main peak depicted in the chromatogram sheets of sensitivity solution and standard solution was of montelukast or montelukast dicyclohexylamine, since the specified name of main peak is montelukast in all the chromatogram sheets. • Submit 6th month stability studies data of drug product since you have submitted the data of only 3 months. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	submitted COA by firm Batch no. is correct. • The eluted main peak depicted in the chromatogram sheets of sensitivity and standard solutions is of Montelukast dicylohexylamine. The relevant chromatogram of Primary USP reference standard of Montelukast dicyclohexylamine with identified peak is attached along-with COA • 6th month stability data has been submitted on 4-10-2022. However duplicate stability data. • Submitted.

Fee for change of title from M/s ICI Pakistan Limited to M/s Lucky Core Industries Limited, Haripur submitted Rs:30000/- Deposit slip# 0735228781

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

167.	Name, address of Applicant / Marketing Authorization Holder	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi
	Name, address of Manufacturing site.	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Indus Pharma (Pvt.) Ltd. issued on the basis of inspection dated 25-01-2025 and valid for 3 years .
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 21-07-2020 specifying Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22139 dated 04-08-2022

	Details of fee submitted	PKR 30,000/- Deposit Slip# 4570831647
	The proposed proprietary name / brand name	**Maxef 2gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone Sodium……2g
	Pharmacotherapeutic Group of (API)	Third-Generation Cephalosporin antibiotics.
	Pharmaceutical form of applied drug	Dry powder for injection
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CEFTRIAXONE by SANDOZ INC of USFDA
	For generic drugs (me-too status)	Oxidil IV Injection 2gm by Sami Pharmaceutical (Pvt.) Ltd, Reg. No. 086609
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical Co., Ltd. No. 849 Dongjia Town, Licheng District, Jinan, Shandong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5% for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Oxidil IV Injection 2gm by Sami Pharmaceutical (Pvt.) Ltd, Reg. No. 086609 by performing quality tests (description, pH, Assay, Microbial Limit).
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. **Address:** No. 15, Donghai 5th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.		
API Lot No.	1066DJ81HG		
Description of Pack (Container closure system)	Packed in 20ml clear glass sealed vial containing dry powder with 10ml WFI		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-1/MXF 2g Inj	TR-2/MXF 2g Inj	TR-3/MXF 2g Inj
Batch Size	2000 vials	2000 vials	2000 vials
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	24-10-2021	24-10-2021	24-10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to onsite inspection report of their product Canazin tablet 300mg which was conducted on 14-03-2019 and was presented in 289th meeting of Registration Board held on 14 – 16th May , 2019 According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software. • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of DML of the firm (No. Lu 20160006) issued by CFDA China. The license is valid till 03-11-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of, form 6, and Commercial Invoice # JTRF210615-MQ dated: 17-06-2021 cleared by DRAP (Karachi) on 30-06-2021 specifying 500Kg of Sterile Ceftriaxone sodium batch # 1066DJ81HG
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Valid GMP certificate is attached
2.	1.5.2	Reference product is available as Each vial contains Ceftriaxone Sodium equivalent to Ceftriaxone 2 g while your applied product is Each vial contains Ceftriaxone Sodium 2 g. Clarification is required.	Revised section 1.5.2 is attached with label claim Each vial contains: Ceftriaxon (as Sodium)…..2g However fee not submitted
3.	3.2.P.2.2.1	In Pharmaceutical equivalence of the applied drug with the innovator / reference / comparator product results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted.	Pharmaceutical equivalence with complete test results mentioned in USP are attached
4.	3.2.P.2.6	Compatibility studies for the dry powder for injections with diluent should be submitted.	Compatibility with Dextrose 5%, NaCl 0.9% and water for Injection is submitted.
5.	3.2.P.5.2	Justify your sample preparation in analytical testing method for assay that how from 10 vials of 2g powder for injection .32mg/ml concentration was prepared.	Revised analytical testing Method is submitted
6.	3.2.P.5.3	Analytical verification studies of 1gm injection submitted.	Revised analytical verification studies are submitted.

Decision: Approved. Firm shall submit fee of Rs. 30,000 for correction/pre-approval correction in formulation (Label claim), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 before issuance of Registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

168.	Name, address of Applicant / Marketing Authorization Holder	**M/s S.J.&G. Fazul Ellahie (Pvt) Ltd., Plot # E-46, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	M/s S.J.&G. Fazul Ellahie (Pvt) Ltd., Plot # E-46, S.I.T.E., Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 02-06-2024 based on inspection conducted on 29-05-2023 and valid for 2 years..
	Evidence of approval of manufacturing facility	Firm has submitted copy of renewal of DML dated 20-09-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24959 dated 02-09-2022
	Details of fee submitted	PKR 30,000/- Deposit Slip# 8887405044
	The proposed proprietary name / brand name	**Silocin Capsule 4mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Silodosin…….4mg
	Pharmacotherapeutic Group of (API)	Alpha Blocker
	Pharmaceutical form of applied drug	White to off white color granules powder filled in hard gelatin capsule, packed in Alu-Alu blister.
	Reference to Finished product specifications	Inhouse specifications
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rapaflo Capsule (USFDA Approved)
	For generic drugs (me-too status)	Sildat Capsule of M/s Sami Pharmaceuticals (Pvt) Ltd., Karachi (Reg.No. 105264)
	Name and address of API manufacturer.	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. **Address:** No. 15, Donghai 5th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5% for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the innovator's product Rapaflo Capsule manufactured by Allergan USA, Inc. performing quality tests (Identification, Physical appearance, Uniformity of weight, Dissolution, Assay). CDP has been performed against the innovator's product Rapaflo Capsule manufactured by Allergan USA, Inc. in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. **Address:** No. 15, Donghai 5th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.		
API Lot No.	13001-200603-2		
Description of Pack (Container closure system)	Alu Alu foil		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-008-21	TR-009-21	TR-012-21
Batch Size	1500 Capsule	1500 Capsule	1500 Capsule
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	26-04-2021	26-04-2021	26-04-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to onsite inspection report of their product D-Lanso Capsule which was conducted on 18-02-2021 and was presented in 307th meeting of Registration Board. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software. • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML No# Zhejiang 20050431 issued by China food and Drug Control administration dated: 17-06-2020 and valid until 16.06.2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of, form 6, and Commercial Invoice # TY12020811238 dated: 11-08-2020 cleared by DRAP (Karachi) on 01-09-2020 specifying 100g of Silodosin batch # 13001-200603-2

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

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Valid GMP certificate of the manufacturing unit submitted.
2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Valid Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin submitted.
3.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Copies of the Drug substance specifications by Drug Product manufacturer are submitted.
4.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
5.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance are submitted.
6.	3.2.P.2.2	Justification shall be submitted for not performing Uniformity of dosage units in pharmaceutical equivalence.	Content Uniformity of Silodosin 4mg are performed against innovator sample and revised Pharmaceutical equivalence submitted.
7.	3.2.P.8	• Submit legible commercial invoice attested by DRAP. • Silodosin is a light sensitive material therefore the whole analytical procedures should avoid exposure to light using brown volumetric flask and sampler vials. Justify the performance of analytical procedures in volumetric flasks and other glassware without taking this precaution. • Record of Digital data logger for temperature and humidity monitoring of stability	• Submitted. • Silodosin is a light sensitive material therefore the whole analytical procedure should avoid exposure to light using brown volumetric flask and other glassware without taking these precautions. (Testing of Silodosin 4mg and 8mg Capsules were performed in amber glassware, there is dedicated glassware for silodosin 4mg and 8mg Capsules but due to typo error protection of standard / samples

		chambers (real time and accelerated)	from light are missing in "Testing Procedure". Testing Procedures of silodosin 4mg and 8mg Capsules have been revised with addition of a "NOTE" (Standard / samples solution protect from light). Revised copy is attached). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) submitted.

Decision: Approved with innovator's specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

169.	Name, address of Applicant / Marketing Authorization Holder	**M/s S.J.&G. Fazul Ellahie (Pvt) Ltd., Plot # E-46, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	M/s S.J.&G. Fazul Ellahie (Pvt) Ltd., Plot # E-46, S.I.T.E., Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 02-06-2024 based on inspection conducted on 29-05-2023 and valid for 2 years..
	Evidence of approval of manufacturing facility	Firm has submitted copy of renewal of DML dated 20-09-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25816 dated 13-09-2022
	Details of fee submitted	PKR 30,000/- Deposit Slip# 802849772065
	The proposed proprietary name / brand name	**Silocin Capsule 8mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Silodosin……8mg
	Pharmacotherapeutic Group of (API)	Alpha Blocker
	Pharmaceutical form of applied drug	White to off white color granules powder filled in hard gelatin capsule, packed in Alu-Alu blister.
	Reference to Finished product specifications	Inhouse specifications
	Proposed Pack size	1 x 10's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rapaflo Capsule (USFDA Approved)
	For generic drugs (me-too status)	Sildat Capsule of M/s Sami Pharmaceuticals (Pvt) Ltd., Karachi (Reg.No. 105265)
	Name and address of API manufacturer.	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. **Address:** No. 15, Donghai 5th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5% for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the innovator's product Rapaflo Capsule manufactured by Allergan USA, Inc. performing quality tests (Identification, Physical appearance, Uniformity of weight, Dissolution, Assay). CDP has been performed against the innovator's product Rapaflo Capsule manufactured by Allergan USA, Inc. in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.
STABILITY STUDY DATA		

Manufacturer of API	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. **Address:** No. 15, Donghai 5th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.		
API Lot No.	13001-200603-2		
Description of Pack (Container closure system)	Alu Alu foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-013-21	TR-014-21	TR-015-21
Batch Size	1500 Capsule	1500 Capsule	1500 Capsule
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	26-04-2021	26-04-2021	26-04-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to onsite inspection report of their product D-Lanso Capsule which was conducted on 18-02-2021 and was presented in 307th meeting of Registration Board. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software. • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML No# Zhejiang 20050431 issued by China food and Drug Control administration dated: 17-06-2020 and valid until 16.06.2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of, form 6, and Commercial Invoice # TY12020811238 dated: 11-08-2020 cleared by DRAP (Karachi) on 01-09-2020 specifying 100g of Silodosin batch # 13001-200603-2
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply

1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Valid GMP certificate of the manufacturing unit submitted.
2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Valid Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin submitted.
3.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Copies of the Drug substance specifications by Drug Product manufacturer are submitted.
4.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
5.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance are submitted.
6.	3.2.P.2.2	Justification shall be submitted for not performing Uniformity of dosage units in pharmaceutical equivalence.	Content Uniformity of Silodosin 8mg are performed against innovator sample and revised Pharmaceutical equivalence submitted.
7.	3.2.P.8	• Submit legible commercial invoice attested by DRAP. • Silodosin is a light sensitive material therefore the whole analytical procedures should avoid exposure to light using brown volumetric flask and sampler vials. Justify the performance of analytical procedures in volumetric flasks and other glassware without taking this precaution. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Submitted. • Silodosin is a light sensitive material therefore the whole analytical procedure should avoid exposure to light using brown volumetric flask and other glassware without taking these precautions. (Testing of Silodosin 4mg and 8mg Capsules were performed in amber glassware, there is dedicated glassware for silodosin 4mg and 8mg Capsules but due to typo error protection of standard / samples from light are missing in "Testing Procedure". Testing Procedures of silodosin 4mg and 8mg Capsules have been revised with addition of a "NOTE" (Standard / samples solution protect from light). Revised copy is attached). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) submitted.

Decision: Approved with innovator's specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, before issuance of registration letter.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
170.	Name, address of Applicant / Marketing Authorization Holder	M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of inspection report for grant of New section dated 28-07-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 12-11-2021 specifying Oral Liquid General section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26103 dated 14-09-2022
	Details of fee submitted	PKR 30,000/- Deposit Slip# 71320721223
	The proposed proprietary name / brand name	**New-Zinc 20mg/5ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Zinc Sulphate Eq. to Elemental Zinc…20mg
	Pharmacotherapeutic Group of (API)	Anti-diarrheal
	Pharmaceutical form of applied drug	Clear transparent to light yellow liquid solution
	Reference to Finished product specifications	USP
	Proposed Pack size	60ml, 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	International pharmacopeia
	For generic drugs (me-too status)	Osiris Syrup 20mg/5ml by Sami Pharmaceutical (Pvt.) Ltd, Reg. No. 066902
	Name and address of API manufacturer.	Rasina Herbs Pvt. Ltd N-2, M.I.D/C. Chemicas Zone, Kupwad, sangli.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties,

		solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30°C ± 2°C / 65% ± 5% for 36 months Accelerated: 40°C ± 2°C / 75% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Osiris Syrup 20mg/5ml by Sami Pharmaceutical by performing quality tests (Description, ,Identification, pH, Uniformity of dosage units, Deliverable volume, Assay,).
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	Rasina Herbs Pvt. Ltd N-2, M.I.D/C. Chemicals Zone, Kupwad, sangli.		
API Lot No.	ZnMop22004		
Description of Pack (Container closure system)	Amber glass bottle USP Type III		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	45 bottles	45 bottles	45 bottles
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	27-09-2021	27-09-2021	27-09-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No.6111495) issued by Food and Drugs issued dated:21-02-2023 and valid till 20-02-2024.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 3, form 7, and Commercial Invoice # E228/21-22 dated: 10-09-2021 specifying 0.5Kg of Zinc Sulphate batch # ZnMop22004
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	1.5.9	Evidence of approval / registration / marketing status of the applied formulation in the same composition, same strength (20mg/5ml) salt form and dosage form in one of the reference regulatory authority specified by Registration Board. The name of the reference authority shall be mentioned as adopted by Board currently.	Available In IP as solution (Available strength: 10mg & 20mg of zinc per 5ml)
2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin submitted.
3.	2.3.R.1.1	Justify Quantity of zinc sulphate dispensed in stability batches and how 1mg of zinc sulphate is equivalent to 2.470mg of elemental zinc.	1mg of elemental zinc is equivalent to 2.745mg of Zinc Sulfate , 2.47mg mentioned by mistake
4.	3.2.S.4.1	Copies of the Drug substance specifications by both Drug substance & Drug Product manufacturer is required.	Submitted
5.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.	Submitted
6.	3.2.P.1	• Provide reference of product which is used for formulation in terms of excipients as WHO prequalified product (zinc sulphate 10mg/5ml) is different than your product in terms of formulation. • How 1mg of zinc sulphate is equivalent to 2.470mg of elemental zinc justify your quantity per 5ml with reference to WHO prequalified product	• We have selected most commonly used excipients for liquid dosage form. We have performed active-Excipient compatibility study. • 1mg of elemental zinc is equivalent to 2.745mg of Zinc Sulfate , 2.47mg mentioned by mistake.

		[Zinc (as sulfate) 10 mg/5 mL oral solution].	
7.	3.2.P.5.3	Analytical method verification studies of drug substance and drug product are same. Clarify how.	Submitted.
8.	3.2.P.8	• Documents for the procurement of API with approval from DRAP. • In COA's of all time points and stability summary sheets in description white colour suspension is mentioned while as per specification it is solution. Clarify.	• Material was directly received at plant through DHL. • In COA's of all time points and stability summary sheets in description white colour suspension is by mistakenly mentioned, It's a solution. Revised COA are attached.

Decision: Approved. Firm shall submit fee of Rs. 30,000 for correction/pre-approval change, in the composition with respect to equivalency factor of drug substance of drug substance, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

171.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceuticals 7KM Pasrur Road Sialkot**
	Name, address of Manufacturing site.	M/s Islam Pharmaceuticals 7KM Pasrur Road Sialkot
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP certificate on the basis of evaluation conducted on dated 08-02-2023 and valid for two years.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 29-08-2018 specifying Tablet General section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24500 dated 30-08-2022
	Details of fee submitted	PKR 30,000/- Deposit Slip# 14786486810
	The proposed proprietary name / brand name	**Diflo Delayed release tablet 50mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Delay release tablet contains: Diclofenac Sodium …….50mg.
	Pharmacotherapeutic Group of (API)	White color, round, biconvex, enteric coated tablets
	Pharmaceutical form of applied drug	Non-steroidal anti-inflammatory drug (NSAIDs)
	Reference to Finished product specifications	USP
	Proposed Pack size	2×10's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Diclofenac Sodium 50mg enteric coated tablet, TEVA Pharmaceutical, MHRA Approved.
	For generic drugs (me-too status)	Dicloran 50mg tablet, SAMI Pharmaceuticals Pvt Limited. Pakistan
	Name and address of API manufacturer.	Shaanxi Xiyue Pharmaceutical Address: Xiyue Production Zone of pharmaceutical factory, West Jishne road, Huayin city, shaanxi province China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5% for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the brand leader that is Voltaren 50mg tablet by Novartis Pharma by performing quality tests (Identification, Assay, Disintegration, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Voltaren 50mg tablet by Novartis Pharma. in Acid media (pH 1.0-1.2) & Acetate buffer 4.5pH and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.
STABILITY STUDY DATA		
Manufacturer of API		Shaanxi Xiyue Pharmaceutical Address: Xiyue Production Zone of pharmaceutical factory, West Jishne road, Huayin city, shaanxi province China

API Lot No.	2007206		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	20TRn021	21TRn008	21TRn009
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	12-2020	06-2021	06-2021
Date of Initiation	24-06-2021	24-06-2021	24-06-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No. SN20190340) issued by NMPA issued dated:25-02-2019 and valid till 24-02-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice # XYCI20201119 dated: 19-11-2020 not Cleared by DRAP (Lahore) specifying 1300g of Diclofenac Sodium batch # 2007206
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Submitted.
2.	3.2.P.1	In reference product anhydrous lactose is used while it is not used in your product. Clarify.	Lactose anhydrous is used as lubricant, while we have used Avicel 102 for the same role in the formulation and have achieved satisfactory result for the physical and chemical attributes of the product during product development and stability studies.
3.	3.2.P.2.2.1	Submit complete Comparative dissolution profile.	Complete comparative dissolution submitted.

4.	3.2.P.8	• Documents for the procurement of API with approval from DRAP. • Reference of previous approval of applications with stability study data of the firm. • Batch # 20TRn021 is manufactured in December-2020 while stability studies started in June 2021. Where product is stored in this period and what are storage conditions.	• Commercial Invoice submitted. • Batch # 20TRn021 was dispensed in Dec-2020, but batch was processed later, Coated tablets were tested on 10th June, 2021 and stability studies were started on 24th June, 2021.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case no. 02 Registration applications of newly granted DML or New section (Human)

a. New DML

M/s Oncogen Pharma Private Limited . **(New DML)**

CLB in its 287th meeting held on 24th June 2022 has considered and approved the grant of Drug Manufacturing License by way of formulation with following Two (02) sections to M/s Oncogen Pharma Private Limited.

1. Tablet (Oncology)
2. Capsule (Oncology)

172.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Oncogen Pharma Private Limited.Plot No # WH 26 and 27-A3, Korangi Creek Industrial Park Karachi.**
	Name, address of Manufacturing site.	M/s Oncogen Pharma Private Limited.Plot No # WH 26 and 27-A3, Korangi Creek Industrial Park Karachi.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Last DML Inspection dated 08-06-2022 concludes as 'GOOD' based on designed and established at an acceptable level of compliance of GMP requirements. Tablet (Anti-cancer) and Capsule (Anti-cancer) sections were approved.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 04-07-2022 specifying Capsule (Oncology) sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking Id: UAP-EN8-9A3W Application No. 1339 dated 12-01-2024
	Details of fee submitted	Rs.30,000/- Deposit slip # 17847637247
	The proposed proprietary name / brand name	**Lemidna Capsule 5mg**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Lenalidomide ……..…. 5mg
	Pharmaceutical form of applied drug	Other immunosuppressant's. ATC code: L04AX04.
	Pharmacotherapeutic Group of (API)	Film coated tablet
	Reference to Finished product specifications	In-house specifications
	Proposed Pack size	3 x 7's
	Proposed unit price	6,000/=
	The status in reference regulatory authorities	REVLIMID by BRISTOL MYERS SQUIBB of (PMDA Approved)
	For generic drugs (me-too status)	Relidomide 5mg Capsule of M/s M/s Helix Pharma
	Name and address of API manufacturer.	M/S Hetero Labs Limited, Unit-I, Sy.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District,Pincode 502319,Telangana State,India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Revlimid 5mg Capsules by Celgene International Sarl. Istanbul Turkey performing quality tests Appearance, , Dissolution, Assay. CDP has been performed against the 'Revlimid 5mg Capsules by Celgene International Sarl. Istanbul Turkey in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for as drug product.
STABILITY STUDY DATA		

Manufacturer of API	M/S Hetero Labs Limited, Unit-I, Sy.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District,Pincode 502319,Telangana State,India		
API Lot No.	LG22090001 LG22110002		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	009NS03-5	009NS04-5	009NS05-5
Batch Size	2290 capsules	2290 capsules	2290 capsules
Manufacturing Date	May-2023	May-2023	May-2023
Date of Initiation	09-06-2023	09-06-2023	09-06-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No . L.Dis.No:91056/TS/2022 issued by DRUGS CONTROL ADMINISTRATION Government of Telangana issued dated: 01/10/2022 valid until 29/09/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 (License To Import Drug(S) For Clinical Trial, Examination, Test Or Analysis) # K-1156156894265, dated; 28-Oct-2022 Commercial Invoice No # S13622227365 dated: 07-01-2023 Ledolinamide batch # LG22090001 & LG22110002
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Shortcoming	Reply
1.	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form i.e., Lenalidomide as Hemihydrate and dosage form in one of the reference regulatory authority specified by Registration Board. The name of the reference authority shall be mentioned as adopted by Board currently.	Firm has referred to the following extract of EMA Public assessment report of the innovator drug product i.e., Revlimid capsules for the description of active substance i.e., Lenalidomide. "It is a synthetic derivative of glutamic acid and is structurally close to thalidomide

		(identical backbone but differs from thalidomide by removing an oxygen from the phthalyl ring and by adding an amine group). Although it is chiral and possesses an asymmetric carbon, it has been developed as a racemic mixture since it undergoes racemisation under physiological conditions. ***It is obtained as a hemihydrate form and is non-hygroscopic."***
2.	Submit fee for revision of label claim	Not submitted.
3.	• Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed.	Firm has submitted Pharmaceutical equivalence studies against the reference product manufactured by i.e. Celgene International (an affiliate company of Bristol-Myers Squibb).
4.	5.174mg of Lenalidomide hemihydrate is equivalent to 5mg of Lenalidomide as per reference product but you have mentioned in your batch formula Lenalidomide 5 mg. Justification is required.	Lenalidomide potency is assigned as Anhydrous basis, hence potency of this molecule is the pure Lenalidomide, without Hemihydrate. During manufacturing, API quantity is calculated on the basis of Anhydrous basis, means the required quantity is added as per Pure Lenalidomide.

Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7,500/- for standardization of label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

173.		
	Name, address of Applicant / Marketing Authorization Holder	**M/s Oncogen Pharma Private Limited.Plot No # WH 26 and 27-A3, Korangi Creek Industrial Park Karachi.**
	Name, address of Manufacturing site.	M/s Oncogen Pharma Private Limited.Plot No # WH 26 and 27-A3, Korangi Creek Industrial Park Karachi.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Last DML Inspection dated 08-06-2022 concludes as 'GOOD' based on designed and established at an acceptable level of compliance of GMP requirements. Tablet (Anti-cancer) and Capsule (Anti-cancer) sections were approved.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 04-07-2022 specifying Capsule (Oncology) sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking Id: NSY-2VY-LJPQ Application No. 1379 dated 12-01-2024
	Details of fee submitted	Rs.30,000/- Deposit slip # 48343990725
	The proposed proprietary name / brand name	**Lemidna Capsule 10mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Lenalidomide …….. 10mg
	Pharmaceutical form of applied drug	Other immunosuppressant's. ATC code: L04AX04.
	Pharmacotherapeutic Group of (API)	Film coated tablet
	Reference to Finished product specifications	In-house specifications
	Proposed Pack size	3 x 7's
	Proposed unit price	12,000/=
	The status in reference regulatory authorities	REVLIMID by BRISTOL MYERS SQUIBB of (EMA Approved)
	For generic drugs (me-too status)	Relidomide 10mg Capsule of M/s M/s Helix Pharma
	Name and address of API manufacturer.	M/S Hetero Labs Limited, Unit-I, Sy.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District,Pincode 502319,Telangana State,India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5%RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Lenaido 10mg Capsule by ATCO Laboratories Ltd. performing quality tests Appearance, , Dissolution, Assay. CDP has been performed against the 'Lenaido 10mg Capsule by ATCO Laboratories Ltd in Acidic media (pH 1.2), Acetate Buffer

		(pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/S Hetero Labs Limited, Unit-I, Sy.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District,Pincode 502319,Telangana State,India		
API Lot No.	LG22090001 LG22110002		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	009N503-10	009N504-10	009N505-10
Batch Size	2428 capsules	2428 capsules	2428 capsules
Manufacturing Date	May-2023	May-2023	May-2023
Date of Initiation	09-06-2023	09-06-2023	09-06-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. L.Dis.No:91056/TS/2022 issued by DRUGS CONTROL ADMINISTRATION Government of Telangana issued dated: 01/10/2022 valid until 29/09/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 (License To Import Drug(S) For Clinical Trial, Examination, Test Or Analysis) # K-1156156894265, dated; 28-Oct-2022 Commercial Invoice No # S13622227365 dated: 07-01-2023 Ledolinmide batch # LG22090001 & LG22110002
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Shortcoming	Reply
1.	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form i.e.,	Firm has referred to the following extract of EMA Public assessment report of the innovator drug product i.e., Revlimid

	Lenalidomide as Hemihydrate and dosage form in one of the reference regulatory authority specified by Registration Board. The name of the reference authority shall be mentioned as adopted by Board currently.	capsules for the description of active substance i.e., Lenalidomide. "It is a synthetic derivative of glutamic acid and is structurally close to thalidomide (identical backbone but differs from thalidomide by removing an oxygen from the phthalyl ring and by adding an amine group). Although it is chiral and possesses an asymmetric carbon, it has been developed as a racemic mixture since it undergoes racemisation under physiological conditions. ***It is obtained as a hemihydrate form and is non-hygroscopic."***
2.	Submit fee for revision of label claim	Not submitted.
3.	Justification shall be submitted for Quantity of Lenalidomide per unit tablet against the equivalency factor	Lenalidomide potency is assigned as Anhydrous basis, then the potency of this molecule is the pure Lenalidomide, without Hemihydrate. During manufacturing, API quantity is calculated on the basis of Anhydrous basis, means the required quantity is added as per Pure Lenalidomide.

Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7,500/- for standardization of label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

174.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Oncogen Pharma Private Limited.** **Plot No # WH 26 and 27-A3, Korangi Creek Industrial Park Karachi.**
	Name, address of Manufacturing site.	M/s Oncogen Pharma Private Limited. Plot No # WH 26 and 27-A3, Korangi Creek Industrial Park Karachi.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Last DML Inspection dated 08-06-2022 concludes as 'GOOD' based on designed and established at an acceptable level of compliance of GMP requirements. Tablet (Anti-cancer) and Capsule (Anti-cancer) sections were approved.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 04-07-2022 specifying Capsule (Oncology) sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Tracking Id: 7H3-5BD-3TM9 Application No. 1340 dated 12-01-2024
	Details of fee submitted	Rs.30,000/- Deposit slip # 5384525451
	The proposed proprietary name / brand name	**Lemidna Capsule 25mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Lenalidomide …….…. 25mg
	Pharmaceutical form of applied drug	Other immunosuppressants. ATC code: L04AX04.
	Pharmacotherapeutic Group of (API)	Film coated tablet
	Reference to Finished product specifications	In-house specifications
	Proposed Pack size	3 x 7's
	Proposed unit price	30,000/=
	The status in reference regulatory authorities	REVLIMID by BRISTOL MYERS SQUIBB of (EMA Approved)
	For generic drugs (me-too status)	Relidomide 25mg Capsule of M/s M/s Helix Pharma
	Name and address of API manufacturer.	M/S Hetero Labs Limited, Unit-I, Sy.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District,Pincode 502319,Telangana State,India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Revlimid 25mg Capsules by Celgene International Sarl. Istanbul Turkey performing quality tests Appearance, , Dissolution, Assay. CDP has been performed against the 'Revlimid 25mg Capsules by Celgene International Sarl. Istanbul Turkey in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.

	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/S Hetero Labs Limited, Unit-I, Sy.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District,Pincode 502319,Telangana State,India		
API Lot No.	LG22090001 LG22110002		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	009N503-25	009N504-25	009N505-25
Batch Size	1450 Capsules	1450 Capsules	1450 Capsules
Manufacturing Date	May-2023	May-2023	May-2023
Date of Initiation	13-06-2023	13-06-2023	13-06-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No . L.Dis.No:91056/TS/2022 issued by DRUGS CONTROL ADMINISTRATION Government of Telangana issued dated: 01/10/2022 valid until 29/09/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 (License To Import Drug(S) For Clinical Trial, Examination, Test Or Analysis) # K-1156156894265, dated; 28-Oct-2022 Commercial Invoice No # S13622227365 dated: 07-01-2023 Ledolinmide batch # LG22090001 & LG22110002
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

1.	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form i.e., Lenalidomide as Hemihydrate and dosage form in one of the reference regulatory authority specified by Registration Board.	Firm has referred to the following extract of EMA Public assessment report of the innovator drug product i.e., Revlimid capsules for the description of active substance i.e., Lenalidomide.

	The name of the reference authority shall be mentioned as adopted by Board currently.	"It is a synthetic derivative of glutamic acid and is structurally close to thalidomide (identical backbone but differs from thalidomide by removing an oxygen from the phthalyl ring and by adding an amine group). Although it is chiral and possesses an asymmetric carbon, it has been developed as a racemic mixture since it undergoes racemisation under physiological conditions. ***It is obtained as a hemihydrate form and is non-hygroscopic."***
2.	Submit fee for revision of label claim	Not submitted.
3.	Justification shall be submitted for Quantity of Lenalidomide per unit tablet against the equivalency factor	Lenalidomide potency is assigned as Anhydrous basis, then the potency of this molecule is the pure Lenalidomide, without Hemihydrate. During manufacturing, API quantity is calculated on the basis of Anhydrous basis, means the required quantity is added as per Pure Lenalidomide.

Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7,500/- for standardization of label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s Biogen Life Sciences. (New DML)

CLB in its 273rd meeting held on 15th January 2020 has considered and approved the grant of Drug Manufacturing License by way of formulation

Tablet (General) Section

175.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences 8-KM, Chak Beli Road, Rawat, Rawalpindi.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences 8-KM, Chak Beli Road, Rawat, Rawalpindi.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate based on the inspection dated 01-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 14-02-2020 specifying Tablet (General) sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking Id: 7H3-5BD-3TM9 Application No. 1340 dated 16-01-2024

	Details of fee submitted	Rs.30,000/- Deposit slip # 1113516715
	The proposed proprietary name / brand name	**Terbigen 125mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablets contain: Terbinafine (as hydrochloride).....125mg
	Pharmaceutical form of applied drug	Antifungal for systemic use
	Pharmacotherapeutic Group of (API)	Film coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Terbinafine 125mg Tablets by Dr. Reddy's Laboratories of (MHRA Approved)
	For generic drugs (me-too status)	Lamisil 125mg Tablet of M/s Novartis Pharma (Pvt)., Ltd. Reg# 013208
	Name and address of API manufacturer.	M/s Tagoor Laboratories PVT., Limited (UNITE-I) Sy No: 29 Tupakulagudem, Pochavaram panchayat Tallapudi, west Godavari, Dist. Andhra Pradesh.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Lamisil 125mg Tablet of Novartis Pharma by performing quality tests Description, Identification, Uniformity of dosage unit , Dissolution, Assay. CDP has been performed against the Lamisil 125mg Tablet of Novartis Pharma in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.

	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Tagoor Laboratories PVT., Limited (UNITE-I) Sy No: 29 Tupakulagudem, Pochavaram panchayat Tallapudi, west Godavari, Dist. Andhra Pradesh.		
API Lot No.	TBH00122		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	20-02-2023	20-02-2023	20-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No# HMF07-15030/45/2023-DD-DDCA issued by DRUGS CONTROL ADMINISTRATION Government of Andhra Pradesh issued dated: 15/05/2023 valid for one year. COPY of DML No # 08/WG/AP/2019/B/G issued by DRUGS CONTROL ADMINISTRATION Government of Andhra Pradesh Dated: 20-03-2019 and valid till 19-03-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 5, [Drug Import License) No. K-355965367643 issued on 25/04/2022 by Drug Regulatory Authority of Pakistan, valid till 24/04/2024 specifying Terbinafine HCl was provided. Firm Submitted form 3, form 7 and Clearance certificate # E-1051748776785 specifying # commercial Invoice # EXP/189/21-22 dated: 31-03-2022 specifying Terbinafine HCl 25Kg batch # TBH00122.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	submitted
2.	3.2.P.2.2.1	Justification shall be submitted for not performing Disintegration in pharmaceutical equivalence.	Revised Pharmaceutical equivalence studies are submitted.
3.	3.2.P.8	• Commercial Invoice for the procurement of API with approval from DRAP. • Initiation date of stability studies not submitted. • Weight used for sample preparation in analytical testing method section 3.2. P. 5.2 and in raw data sheets of stability data is different.	• Procurement documents submitted. • Initiation date of stability studies submitted. • It is stated that the space in raw data sheet are limited due to which details of sample preparation cannot be elaborated in detail. Therefor in raw data sheet we only mentioned the final dilution which is 20mg/100ml =0.2mg/ml whereas the weight of sample stock solution taken is 50mg Terbinafine as mentioned in analytical procedure.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

176.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences 8-KM, Chak Beli Road, Rawat, Rawalpindi.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences 8-KM, Chak Beli Road, Rawat, Rawalpindi.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate based on the inspection dated 01-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 14-02-2020 specifying Tablet (General) sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking Id: BQU-5DA-JR7E Application No. 756 dated 16-01-2024
	Details of fee submitted	Rs.30,000/- Deposit slip # 11238645043

	The proposed proprietary name / brand name	**Terbigen 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablets contain: Terbinafine (as hydrochloride).....250mg
	Pharmaceutical form of applied drug	Antifungal for systemic use
	Pharmacotherapeutic Group of (API)	Film coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Terbinafine 250mg Tablets by Dr. Reddy's Laboratories of (MHRA Approved)
	For generic drugs (me-too status)	Lamisil 250mg Tablet of M/s Novartis Pharma (Pvt)., Ltd. Reg# 013209
	Name and address of API manufacturer.	M/s Tagoor Laboratories PVT., Limited (UNITE-I) Sy No: 29 Tupakulagudem, Pochavaram panchayat Tallapudi, west Godavari, Dist. Andhra Pradesh.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Lamisil 250mg Tablet of Novartis Pharma by performing quality tests Description, Identification, Uniformity of dosage unit , Dissolution, Assay. CDP has been performed against the Lamisil 250mg Tablet of Novartis Pharma in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Tagoor Laboratories PVT., Limited (UNITE-I) Sy No: 29 Tupakulagudem, Pochavaram panchayat Tallapudi, west Godavari, Dist. Andhra Pradesh.		
API Lot No.	TBH00122		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T004	T005	T006
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	21-02-2023	21-02-2023	21-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No# HMF07-15030/45/2023-DD-DDCA issued by DRUGS CONTROL ADMINISTRATION Government of Andhra Pradesh issued dated: 15/05/2023 valid for one year. COPY of DML No # 08/WG/AP/2019/B/G issued by DRUGS CONTROL ADMINISTRATION Government of Andhra Pradesh Dated: 20-03-2019 and valid till 19-03-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 5, [Drug Import License) No. K-355965367643 issued on 25/04/2022 by Drug Regulatory Authority of Pakistan, valid till 24/04/2024 specifying Terbinafine HCl was provided. Firm Submitted form 3, form 7 and Clearance certificate # E-1051748776785 specifying # commercial Invoice # EXP/189/21-22 dated: 31-03-2022 specifying Terbinafine HCl 25Kg batch # TBH00122.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is	submitted

		provided in Module 3 section 3.2.P.8.3	
2.	3.2.P.2.2.1	Justification shall be submitted for not performing Disintegration in pharmaceutical equivalence.	Revised Pharmaceutical equivalence studies are submitted.
3.	3.2.P.8	• Commercial Invoice for the procurement of API with approval from DRAP. • Initiation date of stability studies not submitted. • Weight used for sample preparation in analytical testing method section 3.2. P. 5.2 and in raw data sheets of stability data is different.	• Procurement documents submitted. • Initiation date of stability studies submitted. • It is stated that the space in raw data sheet are limited due to which details of sample preparation cannot be elaborated in detail. Therefor in raw data sheet we only mentioned the final dilution which is 20mg/100ml =0.2mg/ml whereas the weight of sample stock solution taken is 50mg terbinafine as mentioned in analytical procedure.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Cream Section (General)

177.	Name, address of Applicant / Marketing Authorization Holder	M/s Biogen Life Sciences 8-KM, Chak Beli Road, Rawat, Rawalpindi.
	Name, address of Manufacturing site.	M/s Biogen Life Sciences 8-KM, Chak Beli Road, Rawat, Rawalpindi.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate based on the inspection dated 01-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 14-02-2020 specifying Cream Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking Id: MVR-9UJ-GB2J Application No. 758 dated 16-01-2024
	Details of fee submitted	Rs.30,000/- Deposit slip # 61123056
	The proposed proprietary name / brand name	**TERBIGEN Cream 1%**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gm contains: Terbinafine HCl……..10.0mg

	Pharmaceutical form of applied drug	Antifungal Agents
	Pharmacotherapeutic Group of (API)	White, smooth to almost smooth, glossy cream
	Reference to Finished product specifications	JP Spec's
	Proposed Pack size	10gm, 15gm
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LAMISIL1% Cream of (USFDA Approved)
	For generic drugs (me-too status)	Lamisil Cream of M/s Glaxosmithkline Pakistan Reg# 084005
	Name and address of API manufacturer.	M/s Tagoor Laboratories PVT., Limited (UNITE-I) Sy No: 29 Tupakulagudem, Pochavaram panchayat Tallapudi, west Godavari, Dist. Andhra Pradesh.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Terbizam of Biogen Pharma by performing quality tests Description, Identification, Average weight, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Tagoor Laboratories PVT., Limited (UNITE-I) Sy No: 29 Tupakulagudem, Pochavaram panchayat Tallapudi, west Godavari, Dist. Andhra Pradesh.
API Lot No.	TBH00122
Description of Pack (Container closure system)	Aluminium Tube
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 Tubes	500 Tubes	500 Tubes
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	17-03-2023	17-03-2023	17-03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No# HMF07-15030/45/2023-DD-DDCA issued by DRUGS CONTROL ADMINISTRATION Government of Andhra Pradesh issued dated: 15/05/2023 valid for one year. COPY of DML No # 08/WG/AP/2019/B/G issued by DRUGS CONTROL ADMINISTRATION Government of Andhra Pradesh Dated: 20-03-2019 and valid till 19-03-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 5, [Drug Import License) No. K-355965367643 issued on 25/04/2022 by Drug Regulatory Authority of Pakistan, valid till 24/04/2024 specifying Terbinafine HCl was provided. Firm Submitted form 3, form 7 and Clearance certificate # E-1051748776785 specifying # commercial Invoice # EXP/189/21-22 dated: 31-03-2022 specifying Terbinafine HCl 25Kg batch # TBH00122.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Submitted
2.	3.2.S.4.4	Finished product is applied on JP specifications while on drug substance USP specifications are applied. Justify.	The working standard provided with material for trail batch was of USP specification. As the applied product is on JP Specifications. Therefore as per precautionary measure we compare the COA of provided material with Specification of terbinafine HCL raw material given in JP Pharmacopeias .Both of them were found to be identical.

3.	3.2.P.2.2.1	Justification of not performing pharmaceutical Equivalence against Innovator product.	The innovator product pack was not available in market at time of stability studies, so P.E was performed against readily available brand
4.	3.2.P.5.2	Assay was performed with 10 µL each of the sample solution and standard solution as per JP pharmacopeia while you are using 10ml. Clarification is required .	It was typographic error it is actually 10µL.
5.	3.2.P.6	Finished product is applied on JP specifications than how working standard of USP grade used. Justification is required.	The working standard provided with material for trail batch was of USP specification. As the applied product is on JP Specifications. Therefore as per precautionary measure we compare the COA of provided material with Specification of terbinafine HCL raw material given in JP Pharmacopeias .Both of them were found to be identical.
6.	3.2.P.8	Commercial Invoice for the procurement of API with approval from DRAP.	Procurement documents submitted.

Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in analytical testing method as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Lotion Section (General)

178.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences 8-KM, Chak Beli Road, Rawat, Rawalpindi.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences 8-KM, Chak Beli Road, Rawat, Rawalpindi.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 14-02-2020 specifying Lotion Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking Id: 88H-694-448E Application No. 783 dated 16-01-2024
	Details of fee submitted	Rs.30,000/- Deposit slip # 1311945982
	The proposed proprietary name / brand name	**TERBIGEN 1% Lotion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gm contains: Terbinafine hydrochloride ……..10.0mg
	Pharmaceutical form of applied drug	Antifungal Agents

	Pharmacotherapeutic Group of (API)	Colorless to pale yellow clear liquid
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	20ml, 30ml, 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lamisil Lotion 1% by M/s GSK of Netherland approved
	For generic drugs (me-too status)	Cutis Lotion of M/s Tabros Pharma Reg# 067109
	Name and address of API manufacturer.	M/s Tagoor Laboratories PVT., Limited (UNITE-I) Sy No: 29 Tupakulagudem, Pochavaram panchayat Tallapudi, west Godavari, Dist. Andhra Pradesh.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Terbisil Lotion 1%w/w of Saffron Pharmaceuticals by performing quality tests Description, Identification, Volume variation, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Tagoor Laboratories PVT., Limited (UNITE-I) Sy No: 29 Tupakulagudem, Pochavaram panchayat Tallapudi, west Godavari, Dist. Andhra Pradesh.
API Lot No.	TBH00122
Description of Pack (Container closure system)	HDPE bottles
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TB01	TB02	TB03
Batch Size	500 Bottles	500 Bottles	500 Bottles
Manufacturing Date	04-2023	04-2023	04-2023
Date of Initiation	13-04-2023	13-04-2023	13-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No# HMF07-15030/45/2023-DD-DDCA issued by DRUGS CONTROL ADMINISTRATION Government of Andhra Pradesh issued dated: 15/05/2023 valid for one year. COPY of DML No # 08/WG/AP/2019/B/G issued by DRUGS CONTROL ADMINISTRATION Government of Andhra Pradesh Dated: 20-03-2019 and valid till 19-03-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 5, [Drug Import License) No. K-355965367643 issued on 25/04/2022 by Drug Regulatory Authority of Pakistan, valid till 24/04/2024 specifying Terbinafine HCl was provided. Firm Submitted form 3, form 7 and Clearance certificate # E-1051748776785 specifying # commercial Invoice # EXP/189/21-22 dated: 31-03-2022 specifying Terbinafine HCl 25Kg batch # TBH00122.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	1.5.6	Specifications applied are Innovator's specification and reference product provided Lamisil Lotion 1% as solution for cutaneous use while in JP Pharmacopeia Terbinafine HCl solution is for cutaneous application and JP Pharmacopeia general chapter specified that "Liquids and Solutions for Cutaneous Application are liquid preparations intended for application to the skin (including scalp) or nails. Liniments and Lotions are included in this category". Justify your specifications in the light of above.	Our applied product terbinafine lotion is on Innovator Specifications and comparative studies were performed against local me too product (Terebisil) Which is on Innovator specification and is a lotion. Whereas Lamisil lotion was quoted only as RRA reference. ***In Netherland (RRA)Lamisil Lotion 1%, solution for cutaneous use mentioned. while in JP Pharmacopeia Terbinafine HCl solution is for cutaneous application and JP Pharmacopeia general chapter specified that "Liquids and Solutions for***

			Cutaneous Application are liquid preparations intended for application to the skin (including scalp) or nails. Liniments and Lotions are included in this category. JP Assay limits are 95.0% and not more than 105.0% while applicant Assay limits are 90.0% to 110.0%.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided
3.	3.2.P.2.2.1	In Pharmaceutical Equivalence Assay value should be mentioned instead of comply.	Revised Pharmaceutical Equivalence with value of assay submitted.
4.	3.2.P.5.3	Finished product assay method is by UV while analytical validation is done by HPLC. Clarification is required.	Revised analytical method according to raw data sheet and validation of analytical procedure is attached.
5.	3.2.P.5.4	In COA's and stability studies Colourless to pale yellow clear liquid mentioned while in specification and in section 3.2.P.1 White, smooth to almost smooth, glossy Lotion mentioned. Clarify	The description of finished product mentioned in raw data sheets is due to clerical mistake; whereas the description of our finished drug product is White, smooth glossy Lotion as mentioned in 3.2.P.1. Therefore this description should be considered in our product stability data
6.	3.2.P.8	• Commercial Invoice for the procurement of API with approval from DRAP. • Stability studies raw data does not match with analytical testing method. Analytical testing method of assay is by UV while submitted stability data is by HPLC. Clarify.	• Procurement documents of API are in enclosed. • Revised analytical method according to raw data sheet and validation of analytical procedure is attached

2nd communication

S.No	Section	Shortcoming	Reply
1.	3.2.P.5.2 & 3.2.P.8	Applied label claim is 1gm contains 10mg of Terbinafine HCl, while in Analytical testing method and stability studies raw data sheets 1ml is dispensed for sample preparation. Clarify.	It is stated that the label claim of our applied product TERBIGEN Lotion 1% w/w is as under Each gm contains: Terbinafine hydrochloride.....10.0mg Whereas in raw data sheets and analytical method it was mistakenly mentioned as Iml contains 10mg of terbinafine HCl. As rectification of the mistake each ml is being replaced with each gm in raw data sheets and analytical method. The revised analytical method according to the label claim is being submitted.

Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in analytical testing method as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s Pine Pharmaceuticals. (New DML)
CLB in its 285th meeting held on 17th and 18th March 2022 has considered and approved the grant of Drug Manufacturing License by way of formulation with following three (03) sections to M/s Pine Pharmaceuticals

1.	Tablet (General)
2.	Capsule (General)
3.	Cream Ointment (General)

Accordingly, firm has applied for following products for consideration by Drug Registration Board

Pine pharma
Cream Section (General)

179.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 29-04-2022 specifying Cream Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking Id: G2L-7EQ-SGBX Application No. 833 dated 20-12-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 33628409
	The proposed proprietary name / brand name	**TERBIPINE 1% CREAM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: Terbinafine hydrochloride……1%w/w(10mg)
	Pharmaceutical form of applied drug	Antifungal
	Pharmacotherapeutic Group of (API)	White to off white colored cream
	Reference to Finished product specifications	JP Spec's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LAMISIL1% Cream of (MHRA Approved)
	For generic drugs (me-too status)	Lamisil Cream of M/s Glaxosmithkline Pakistan Reg# 084005

	Name and address of API manufacturer.	M/s Tagoor Laboratories PVT., Limited (UNITE-I) Sy No: 29 Tupakulagudem, Pochavaram panchayat Tallapudi, west Godavari, Dist. Andhra Pradesh.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Cutis 1% Cream of Tabros Pharma Pakistan by performing quality tests Description, Identification, Uniformity of dosage units, , Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Tagoor Laboratories PVT., Limited (UNITE-I) Sy No: 29 Tupakulagudem, Pochavaram panchayat Tallapudi, west Godavari, Dist. Andhra Pradesh.		
API Lot No.	TBH-0020421		
Description of Pack (Container closure system)	Aluminium Tube		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	200 Tubes(10g)	200 Tubes(10g)	200 Tubes(10g)

Manufacturing Date	05-2023	05-2023	05-2023
Date of Initiation	10-05-2023	10-05-2023	10-05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No# HMF07-15030/45/2023-DD-DDCA issued by DRUGS CONTROL ADMINISTRATION Government of Andhra Pradesh issued dated: 15/05/2023 valid for one year. COPY of DML No # 08/WG/AP/2019/B/G issued by DRUGS CONTROL ADMINISTRATION Government of Andhra Pradesh Dated: 20-03-2019 and valid till 19-03-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between Pine pharmaceuticals and panacea pharmaceuticals submitted. Firm has submitted copy of Commercial Invoice # EXP/034/21-22, dated; 02-08-2021 specify approved by DRAP Islamabad office date: 08-09-2021 specifying 50Kg of Terbinafine HCl batch # TBH-0020421 (panacea pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail report for product testing submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	3.2.S.4.1	Copies of the Drug substance specifications of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Copies of the Drug substance specifications of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted
2.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is submitted.
3.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	Analytical method verification of drug substance submitted.
4.	3.2.S.4.4	Finished product is applied on JP specifications while on drug substance USP specifications are applied. Justify.	The JP and USP are both widely recognized pharmacopeia's that provide standards for the quality, purity, strength, and consistency of pharmaceuticals. While they share many similarities, there may be slight differences in specific requirements or testing methods. Therefore, using JP specifications the finished product and USP specifications for the drug substance

			ensures alignment with the relevant pharmacopeia standards for each component.
5.	3.2.P.2.2.1	Justification of not performing pharmaceutical Equivalence against Innovator product.	We have performed the equivalence study against innovator product, already attached in module-3, section 3.2.P.2.2.1. attached again in the attachment 4
6.	3.2.P.5.2	Provide Sample and standard solution in analytical testing method of assay .	Sample and standard solution in analytical testing method of assay as per JP monograph submitted
7.	3.2.P.6	Finished product is applied on JP specifications than how working standard of USP grade used.	The finished product may conform to JP specifications, using a USP-grade working standard can offer practical benefits such as availability, quality- and compatibility with industry practices.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s Qadir Pharmaceuticals**. (New DML)**

CLB in its 282nd meeting held on 31st August 2021 has considered and approved the grant of Drug Manufacturing License by way of formulation with following seven (07) sections to M/s Qadir Pharmaceuticals

1. Tablet (General)
2. Capsule (General)
3. Oral Liquid (General)
4. Liquid Injectable – Vial & Ampoule (General)
5. Capsule (Cephalosporin)
6. Dry Powder Injectable (Cephalosporin)
7. Oral Dry Powder Suspension (Cephalosporin)

Accordingly, firm has applied for following products for consideration by Drug Registration Board

Tablet Section (General)

180.	Name, address of Applicant / Marketing Authorization Holder	M/s Qadir Pharmaceuticals Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 14-02-2020 specifying Cream Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking Id: M1Y-QNY-T2R6 Application No. 1498 dated 16-01-2024
	Details of fee submitted	Rs.30,000/- Deposit slip # 3150282053
	The proposed proprietary name / brand name	**Epilept 100mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Lacosamide…….…….100mg
	Pharmaceutical form of applied drug	Antiepileptic agent
	Pharmacotherapeutic Group of (API)	white color round shape film coated tablet, plain on both sides.
	Reference to Finished product specifications	USP
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vimpat 100mg tablets by UCB Pharma Limited of (MHRA Approved)
	For generic drugs (me-too status)	Lacolep of M/s Hilton Pharma (Reg# 073858)
	Name and address of API manufacturer.	M/s Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist,
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the LACOLEP 100mg of Hilton Pharma Pakistan by performing quality tests Physical appearance, Identification, Disintegration time , Uniformity of dosage units, , Assay, Dissolution) CDP has been performed against the 'LACOLEP 100mg of Hilton Pharma Pakistan in Acidic media (pH 1.2), Acetate Buffer (pH 4.5)

		& Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist,		
API Lot No.	LE2210006		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTR046	TTR047	TTR048
Batch Size	1008 (Tablet)	1008 (Tablet)	1008 (Tablet)
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	15-02-2023	15-02-2023	15-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	COPY of DML (form 25) No # TS/KRY/2019-53805 issued by DRUGS CONTROL ADMINISTRATION Government of Telangana dated: 15-11-2019 and valid till 14-11-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 6, [License to Import Drug(s) for Clinical Trial, Examination, Test or Analysis no. K- K-1458307553412 issued on 12/01/2023 by Drug Regulatory Authority of Pakistan, Karachi valid till 11/01/2025 specifying LACOSAMIDE was provided. Firm has submitted copy of form 3, form 7 and Commercial Invoice # 22-23/U-l/E-030, dated; 23-12-2023 not cleared by DRAP specifying 1.5Kg of Lacosamide batch # LE2210006
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail report for product testing submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug	The copy of batch manufacturing record (BMR) for all the batches of drug products

		product for which stability studies data is provided in Module 3 section 3.2.P.8.3	for witch stability study data is provided are attached.
2.	3.2.S.4.1	Copies of the Drug substance specifications of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Specifications of the drug substance/Active pharmaceutical ingredient by drug product manufacturer is attached.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedure used for routine testing of drug substance /Active pharmaceutical ingredient by drug product manufacturer is attached. *Firm claimed Ph. Eur while submitted method is as per USP monograph of drug product also Detection is at 215nm which is used for drug product (tablet) while drug substance Detection is at 258nm and concentration of standard and sample preparation are change from pharmacopeia.*
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) of drug substance performed by the drug product manufacturer. *Verification studies of previously submitted for drug product is submitted for drug substance*.
5.	3.2.S.4.4	Certificate of Analysis (CoA) of the same batch of Drug Substance by both Drug substance manufacturer and Drug Product manufacturer used during product development and stability studies.	Certificate of analysis (COA) of the same batch of drug substance by both drug substance manufacturer and drug product manufacturer used during product development and stability studies are attached.
6.	3.2.S.5	Submitted COA of working standard shows validity up to 06-11-2022 while import documents shows manufacturing of drug substance Lacosamide in November, 2022. Justification is required how that working standard used.	Submitted COA of working standard shows validity up to January 2024 and Mfg. date is march 2021. For justification COA of working standard used.
7.	3.2.S.7.3	Submit drug substance stability studies till shelf life for 3 batches.	Drug substance stability studies till shelf life for three batches is attached.
8.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product	Compatibility studies of the drug substance(s) with excipients is attached

9.	3.2.P.5.3	Concentration of sample and standard solution in analytical testing method verification are not as per USP monograph.	Concentration of sample and standard solution in analytical testing method verification are not as per USP but rest of parameter is same so this has not affected the result at the end. *Method in verification studies submitted as per USP monograph . Concentrations of sample and standard are also as per USP monograph that is 1mg/ml but in performance concentration for 100 % in accuracy and precision is 0.02mg/ml which is different from their method.*
10.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary/secondary reference standard including source and Lot number is attached.
11.	3.2.P.8	Documents for the procurement of API with approval from DRAP	Documents for the procurement of API are attached.

Decision: Deferred for submission of following:

- **Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer.**
- **Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.**
- **Justification for using different concentrations of sample and standard solution from that recommended by USP Monograph while performing the verification studies of assay method.**

181.	Name, address of Applicant / Marketing Authorization Holder	M/s Qadir Pharmaceuticals Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 17-09-2021 specifying Tablet Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking Id: X15-U94-5UBG Application No. 1493 dated 12-02-2024
	Details of fee submitted	Rs.30,000/- Deposit slip # 40000970065
	The proposed proprietary name / brand name	**Epilept 50mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Lacosamide…….50mg
	Pharmaceutical form of applied drug	white color round shape film coated tablet, plain on both sides.
	Pharmacotherapeutic Group of (API)	Antiepileptic agent

	Reference to Finished product specifications	USP
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vimpat 50mg tablets by UCB Pharma Limited of (MHRA Approved)
	For generic drugs (me-too status)	Lacolep of M/s Hilton Pharma (Reg# 073857)
	Name and address of API manufacturer.	M/s Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist,
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the LACOLEP 50mg of Hilton Pharma Pakistan by performing quality tests Physical appearance, Identification, Disintegration time , Uniformity of dosage units, , Assay, Dissolution) CDP has been performed against the 'LACOLEP 50mg of Hilton Pharma Pakistan in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist,
API Lot No.	LE2210006
Description of Pack (Container closure system)	Alu-Alu Blister

Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTR043	TTR044	TTR045
Batch Size	1008 (Tablet)	1008 (Tablet)	1008 (Tablet)
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	14-02-2023	14-02-2023	14-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	COPY of DML (form 25) No # TS/KRY/2019-53805 issued by DRUGS CONTROL ADMINISTRATION Government of Telangana dated: 15-11-2019 and valid till 14-11-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 7 and Commercial Invoice # 22-23/U-l/E-030, dated; 23-12-2023 not cleared by DRAP specifying 1.5Kg of Lacosamide batch # LE2210006
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail report for product testing submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	The copy of batch manufacturing record (BMR) for all the batches of drug products for witch stability study data is provided are attached.
2.	3.2.S.4.1	Copies of the Drug substance specifications of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Specifications of the drug substance/Active pharmaceutical ingredient by drug product manufacturer is attached.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedure used for routine testing of drug substance /Active pharmaceutical ingredient by drug product manufacturer is attached. *Firm claimed Ph. Eur while submitted method is as per USP monograph of drug*

			product also Detection is at 215nm which is used for drug product (tablet) while drug substance Detection is at 258nm and concentration of standard and sample preparation are change from pharmacopeia.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) of drug substance performed by the drug product manufacturer. *Verification studies of previously submitted for drug product is submitted for drug substance*.
5.	3.2.S.5	Submitted COA of working standard shows validity up to 06-11-2022 while import documents shows manufacturing of drug substance Lacosamide in November, 2022. Justification is required how that working standard used.	Submitted COA of working standard shows validity up to January 2024 and Mfg. date is march 2021. For justification COA of working standard used.
6.	3.2.S.7.3	Submit drug substance stability studies till shelf life for 3 batches.	Drug substance stability studies till shelf life for three batches is attached.
7.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product	Compatibility studies of the drug substance(s) with excipients is attached
8.	3.2.P.2.2.1	2 different buffers and pH i.e Citrate buffer with pH 6.6 & Phosphate buffer with pH 6.8 are mentioned in Comparative dissolution profile . Clarify which buffer is used in Comparative dissolution profile. Clarification is required.	Phosphate buffer with pH 6.8 is used in comparative dissolution profile. May be there is some mistake in writing the correct CDP is attached.
9.	3.2.P.5.3	Concentration of sample and standard solution in analytical testing method verification are not as per USP monograph.	Concentration of sample and standard solution in analytical testing method verification are not as per USP but rest of parameter is same so this has not affected the result at the end. *Method in verification studies submitted as per USP monograph . Concentrations of sample and standard are also as per USP monograph that is 1mg/ml but in performance concentration for 100 % in accuracy and precision is 0.02mg/ml which is different from their method.*

10.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary/secondary reference standard including source and Lot number is attached.
11.	3.2.P.8	Documents for the procurement of API with approval from DRAP	Documents for the procurement of API are attached.

Decision: Deferred for submission of following:

- **Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer.**
- **Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.**
- **Justification for using different concentrations of sample and standard solution from that recommended by USP Monograph while performing the verification studies of assay method.**

182.		
	Name, address of Applicant / Marketing Authorization Holder	M/s Qadir Pharmaceuticals Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 17-09-2021 specifying Tablet Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking Id: X7G-YX1-D7VW Application No. 1520 dated 12-02-2024
	Details of fee submitted	Rs.30,000/- Deposit slip # 034819025601
	The proposed proprietary name / brand name	**Epilept 150mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Lacosamide…….…….150mg
	Pharmaceutical form of applied drug	white color round shape film coated tablet, plain on both sides.
	Pharmacotherapeutic Group of (API)	Antiepileptic agent
	Reference to Finished product specifications	USP
	Proposed Pack size	14’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vimpat 150mg tablets by UCB Pharma Limited of (MHRA Approved)
	For generic drugs (me-too status)	Lacolep of M/s Hilton Pharma (Reg# 073859)
	Name and address of API manufacturer.	M/s Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist,
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general

		properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the LACOLEP 150mg of Hilton Pharma Pakistan by performing quality tests Physical appearance, Identification, Disintegration time , Uniformity of dosage units, , Assay, Dissolution) CDP has been performed against the 'LACOLEP 150mg of Hilton Pharma Pakistan in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist,		
API Lot No.	LE2210006		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTR049	TTR050	TTR051
Batch Size	1008 (Tablet)	1008 (Tablet)	1008 (Tablet)
Manufacturing Date	02-2023	02-2023	02-2023

Date of Initiation	15-02-2023	14-02-2023	14-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	COPY of DML (form 25) No # TS/KRY/2019-53805 issued by DRUGS CONTROL ADMINISTRATION Government of Telangana dated: 15-11-2019 and valid till 14-11-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 7 and Commercial Invoice # 22-23/U-l/E-030, dated; 23-12-2023 not cleared by DRAP specifying 1.5Kg of Lacosamide batch # LE2210006
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail report for product testing submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	The copy of batch manufacturing record (BMR) for all the batches of drug products for witch stability study data is provided are attached.
2.	3.2.S.4.1	Copies of the Drug substance specifications of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Specifications of the drug substance/Active pharmaceutical ingredient by drug product manufacturer is attached.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedure used for routine testing of drug substance /Active pharmaceutical ingredient by drug product manufacturer is attached. *Firm claimed Ph. Eur while submitted method is as per USP monograph of drug product also Detection is at 215nm which is used for drug product (tablet) while drug substance Detection is at 258nm and concentration of standard and sample preparation are change from pharmacopeia.*
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product	Analytical method verification studies including specificity, accuracy and repeatability (method precision) of drug substance performed by the drug product manufacturer.

		manufacturer drug substance(s) shall be submitted.	*Verification studies of previously submitted for drug product is submitted for drug substance*.
5.	3.2.S.5	Submitted COA of working standard shows validity up to 06-11-2022 while import documents shows manufacturing of drug substance Lacosamide in November, 2022. Justification is required how that working standard used.	Submitted COA of working standard shows validity up to January 2024 and Mfg. date is march 2021. For justification COA of working standard used.
6.	3.2.S.7.3	Submit drug substance stability studies till shelf life for 3 batches.	Drug substance stability studies till shelf life for three batches is attached.
7.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product	Compatibility studies of the drug substance(s) with excipients is attached
8.	3.2.P.2.2.1	2 different buffers and pH i.e Citrate buffer with pH 6.6 & Phosphate buffer with pH 6.8 are mentioned in Comparative dissolution profile . Clarify which buffer is used in Comparative dissolution profile. Clarification is required.	Phosphate buffer with pH 6.8 is used in comparative dissolution profile. May be there is some mistake in writing the correct CDP is attached
9.	3.2.P.5.3	Concentration of sample and standard solution in analytical testing method verification are not as per USP monograph.	Concentration of sample and standard solution in analytical testing method verification are not as per USP but rest of parameter is same so this has not affected the result at the end. *Method in verification studies submitted as per USP monograph. Concentrations of sample and standard are also as per USP monograph that is 1mg/ml but in performance concentration for 100 % in accuracy and precision is 0.02mg/ml which is different from their method.*
10.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary/secondary reference standard including source and Lot number is attached.
11.	3.2.P.8	Documents for the procurement of API with approval from DRAP	Documents for the procurement of API are attached.

Decision: Deferred for submission of following:

- **Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer.**
- **Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.**

- **Justification for using different concentrations of sample and standard solution from that recommended by USP Monograph while performing the verification studies of assay method.**

M/s WORLD BIZ PHARMACEUTICALS**. (New DML)**

CLB in its 282nd meeting held on 31st August 2021 has considered and approved the grant of Drug Manufacturing License by way of formulation with following One (01) sections to M/s WORLD BIZ PHARMACEUTICALS
1. Oral Liquid Syrup Section (General)

Accordingly, firm has applied for following products for consideration by Drug Registration Board

Oral Liquid Syrup Section (General)

183.	Name, address of Applicant / Marketing Authorization Holder	M/s World Biz Pharmaceutical Plot No. 340, Industrial Estate,Phase-II, Multan.
	Name, address of Manufacturing site.	M/s World Biz Pharmaceutical Plot No. 340, Industrial Estate,Phase-II, Multan.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 17-09-2021 specifying Oral Liquid Syrup Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking Id: S8H-78G-MA4W Application No. 797 dated 29-1022023
	Details of fee submitted	Rs.30,000/- Deposit slip # 3501249450
	The proposed proprietary name / brand name	**Onsno Syrup 4mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains:- Ondansetron hydrochloride dihydrate equivalent to Ondansetron…… 4mg
	Pharmaceutical form of applied drug	5-HT3 antagonist, Antiemetic
	Pharmacotherapeutic Group of (API)	Clear transparent with strawberry characteristic flavor and sweet taste.
	Reference to Finished product specifications	USP
	Proposed Pack size	30ml, 50ml, 60ml, 90ml, 100ml, 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ondansetron 4 mg/5 ml Syrup by Syri Limited UK of (MHRA Approved)
	For generic drugs (me-too status)	Onseron Syrup 4mg/5ml of M/s Indus Pharma (Reg# 058677)
	Name and address of API manufacturer.	M/s Anugraha Chemicals No. D-47 to D-50, C-62 & C-63, KSSIDC Industrial Estate, Doddaballapur, Banglore-561203, Karnataka, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of

		manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Onseron Syrup of Indus Pharma by performing quality tests Description, Identification, Color, pH, MICROBAIL TEST, , Assay)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist,		
API Lot No.	AOND-22006		
Description of Pack (Container closure system)	Amber glass bottle + Aluminium cap		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-OS-001	RD-OS-002	RD-OS-003
Batch Size	500 Bottles	500 Bottles	500 Bottles
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	04-01-2023	04-01-2023	04-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of License No. DCD/MFG/Application Id-240 for M/s Anugraha Chemicals, issued by Drug Control Administration Karnataka India valid till 13-02-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Agreement for API's Loan between M/s World Biz Pharmaceutical and DeMont Research Laboratories submitted. Firm has submitted copy of form 5 (Drug Import License) No# K-486022802639 dated: 07-06-2022 and Clearance certificate # E-2278922801827, dated; 17-08-2022 specifying Invoice No # EXP-11 dated: 03-08-2022 Ondansetron hydrochloride batch #. AOND-22006 (DeMont Research Laboratories)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail report for product testing submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	3.2.S.4.4	Specification claimed in section 3.2.S.4.1 are USP while in COA BP specification are mentioned by drug product manufacturer. Clarification is required that which specifications are followed for drug substance by drug product manufacturer.	Specifications adopted by the drug product manufacturer for drug substance testing was based on USP. Revised COA of drug substance is attached.
2.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.	Preservative effectiveness studies are attached.
3.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with Glycerin shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.	Compatibility studies of Drug substance with glycerin was done by FTIR and its spectrum is attached.
4.	3.2.P.4.1	Submit testing of Sorbitol and Glycerin for DEG and EG clearly stating the limits.	Testing reports of Sorbitol and Glycerin are attached from their vendor. *Sorbitol by vendor on BP specification while BP monograph does not mention DEG and EG limits. Glycerin COA by vendor submitted but does not specify which Pharmacopeia follows. COA of Sorbitol and Glycerin by drug product manufacture is not submitted.*

5.	3.2.P.5.1	Microbial Enumeration test and test for specified organism are not part of specification while claimed specifications are USP.	Revised Specification is attached
6.	3.2.P.5.2	In analytical testing method of deliverable volume "Reconstitute the contents of 10 bottles as directed over the label and shake the contents individually" mentioned while applied product is syrup. Clarify how syrup can be reconstituted.	Revised analytical method is attached.
7.	3.2.P.8	In stability studies summary sheets initial testing done on 01-03-2023 than how 3rd month testing done on 04-04-2023. Clarify.	There was a typographic error in date of initial testing which was performed on 03-01-2023. Revised summary data sheets are attached

Decision: Approved. Firm shall submit the fee of Rs. 7,500 for correction in analytical testing method before issuance of registration letter, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s Medevo (Private) Ltd. . **(New DML)**
CLB in its 288th meeting held on 18th October 2022 has considered and approved the grant of Drug Manufacturing License by way of formulation with following Two (02) sections to M/s Medevo (Private) Ltd.

1) Eye Drops (General)
2) Eye Ointment (General)

Eye Ointment (General

184	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.**
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking Id: UAP-EN8-9A3W Application No. 2464 dated 11-03-2024
	Details of fee submitted	PKR 30,000/- : Deposit slip # 0546467058
	The proposed proprietary name / brand name	**SURGIVIR EYE OINTMENT**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gm contains: Acyclovir ……. 30 mg
	Pharmacotherapeutic Group of (API)	Antiviral
	Reference to Finished product specifications	BP

EVALUATION OF DATA

GMP status of the firm	New DML issued dated: 08-11-2022
Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Ointment (General) Section

Proposed Pack size	4.5 gm		
Proposed unit price	As per SRO		
The status in reference regulatory authorities	AVACLYR ophthalmic ointment 3% of (USFDA Approved)		
For generic drugs (me-too status)	LOVIR EYE OINTMENT by Remington Pharmaceutical Industries		
Name and address of API manufacturer.	Zhejiang Zhebei Pharmaceuticals Co., Ltd, Sanlitang Qianyuan Town Deqing County, Zhejiang Province Wenling, 313200, Huzhou City, Zhejiang, China		
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.		
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.		
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.		
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.		
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Lovir Eye Ointment of Remington Pharmaceutical		
Analytical method validation/verification of product			
STABILITY STUDY DATA			
API Lot No.	A210804		
Description of Pack (Container closure system)	Collapsible Aluminum tube		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ACY-Trial001	ACY-Trial002	ACY-Trial003
Batch Size	5Kg (1000 Packs)	5Kg (1000 Packs)	5Kg (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	23-01-2023	23-01-2023	23-01-2023
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
Reference of previous approval of applications with stability study data of the firm (if any)			
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML of M/s Zhejiang Zhebei Pharmaceutical Co., Ltd.-China issued by Zhejiang province NMPA valid till 06-01-2026		

Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of agreement for Loan of Drug substance with Valor Pharmaceuticals. Firm submitted copy of commercial invoice# 1121031240169 dated 01-09-2021 specifying Acyclovir Specifying batch # A210804
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC (No.IV):

S.No	Section	Shortcoming	Reply
1.	1.5.6	Applied on USP specifications while product is not available in USP Pharmacopeia.	USP is mistakenly written. We have applied on BP specifications.
2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin submitted.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted.
5.	3.2.P,5.2	Detailed analytical procedures used for testing the drug product shall be provided.	Detailed analytical procedures used for testing of the drug product are submitted.
6.	3.2.P.5.3	Submit analytical method verification report	Analytical method verification report is submitted.
7.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary / secondary reference standard is submitted.
8.	3.2.P.8	Documents for the procurement of API with approval from DRAP and agreement for loan of material.	Documents for the procurement of API are submitted.

Decision: Approved. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

185	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.**
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking Id: 5SV-7MT-NGZX Application No. 1518 dated 21-02-2024
	Details of fee submitted	PKR 30,000/- : Deposit slip # **04468975**
	The proposed proprietary name / brand name	**Surgitob-D Eye Ointment (0.3 % Tobramycin and 0.1%Dexamethasone)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gm contains: Tobramycin ……. 3 mg Dexamethasone…….1 mg
	Pharmacotherapeutic Group of (API)	Antibiotic and Steroid
	Reference to Finished product specifications	USP Specifications

EVALUATION OF DATA

GMP status of the firm	New DML issued dated: 08-11-2022
Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Ointment (General) Section
Proposed Pack size	3.5 gm
Proposed unit price	As per SRO
The status in reference regulatory authorities	TobraDex Ointment by Novartis Pharmaceuticals of (USFDA Approved)
For generic drugs (me-too status)	Santodex Eye Ointmen by Sante Private Limited
Name and address of API manufacturer.	**Tobramycin:** M/s Chongqing Daxin Pharmaceuticals Co.Ltd.BeiBei, ChongQing people Republic of China. **Dexamethasone:** Zhejiang Xianju Pharmaceutical Co., Ltd 15 West Fengxi Road, Modern Industrial Park, Xianju, Zhejiang-China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Tobramycin: Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions. Dexamethasone: Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions

Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.		
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Santodex Eye Ointment of Sante Private Limited.		
Analytical method validation/verification of product			
STABILITY STUDY DATA			
API Lot No.	Tobramycin: 08191203-U Dexamethasone: X5-161102		
Description of Pack (Container closure system)	Collapsible Aluminum tube		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TMEE-TRIAL001	TMEE-TRIAL002	TMEE-TRIAL003
Batch Size	3.5 kg (1000 Packs)	3.5 kg (1000 Packs)	3.5 kg (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	14-12-2022	14-12-2022	14-12-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
Reference of previous approval of applications with stability study data of the firm (if any)			
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Tobramycin: Copy of DML# Chongqing 20150039 issued by NMPA dated: 22-12-2022 and valid till 15-11-2025 submitted Dexamethasone: Firm has submitted copy of GMP certificate # ZJ20190093 issued by NDMA valid till 04-08-2024.		
Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between Medevo (Pvt) Limited and Innovotek pharmaceuticals submitted. Firm has submitted copy of Clearance certificate # specifying Invoice #PHL206738, dated; 10-03-2020 specifying Tobramycin base Batch #.08191203-U Firm has submitted copy of Commercial Invoice # XJWH1611161PPK, attested by DRAP (Lahore) specifying Dexamethason Batch #. X5-161102		
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.		

Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC (No.IV):

S.No	Section	Shortcoming	Reply
1.	1.3.5	Evidence of separate dispensing booth for steroids.	Inspection report is attached.
2.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) shall be submitted for both Tobramycin and dexamethasone.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both drug substance(s) Tobramycin and dexamethasone is submitted.
3.	3.2.S.4.4	Submitted COA of Dexamethasone show expiry on 05-11-2022 than how testing on 16-11-2022 can be conducted.	Revised COA is submitted.
4.	3.2.P,5.2	Detailed analytical procedures used for testing the drug product shall be provided.	Detailed analytical procedures used for testing of the drug product are submitted.
5.	3.2.P.5.3	Submit analytical method verification report	Analytical method verification report is submitted.
6.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided for both Tobramycin and dexamethasone.	COA of primary / secondary reference standard for both Tobramycin and dexamethasone are submitted.
7.	3.2.P.8	Documents for the procurement of API with approval from DRAP and agreement for loan of material for dexamethasone.	Documents for the procurement of API is submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Eye Drops (General)

186	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.**
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking Id: 1MQ-7LP-DQ9D Application No. 1463 dated 21-02-2024
	Details of fee submitted	PKR 30,000/- : Deposit slip # **469610975487**

	The proposed proprietary name / brand name	SURGITOB-D EYE DROP (0.3 %Tobramycin and 0.1%Dexamethasone Ophthalmic Suspension USP)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Tobramycin ……. 3 mg Dexamethasone…….1 mg
	Pharmacotherapeutic Group of (API)	Antibiotic and Steroid
	Reference to Finished product specifications	USP Specifications

EVALUATION OF DATA			
GMP status of the firm	New DML issued dated: 08-11-2022		
Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section		
Proposed Pack size	5ml		
Proposed unit price	As per SRO		
The status in reference regulatory authorities	TobraDex ophthalmic suspension by Novartis Pharmaceuticals of (USFDA Approved)		
For generic drugs (me-too status)	TobraDex Eye Drop by NOVARTIS Pharmaceutical		
Name and address of API manufacturer.	**Tobramycin:** M/s Chongqing Daxin Pharmaceuticals Co.Ltd.BeiBei, ChongQing people Republic of China. **Dexamethasone:** Zhejiang Xianju Pharmaceutical Co., Ltd 15 West Fengxi Road, Modern Industrial Park, Xianju, Zhejiang-China		
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.		
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.		
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Tobramycin: Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions. Dexamethasone: Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions		
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.		
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the TobraDex ophthalmic Suspension of Novartis PHARMACEUTICALS LABORATORIES.		
Analytical method validation/verification of product			
STABILITY STUDY DATA			
API Lot No.	Tobramycin: 08191203-U Dexamethasone: X5-161102		
Description of Pack (Container closure system)	HDPE bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TMO-TRIAL001	TMO-TRIAL002	TMO-TRIAL003

Batch Size	5 L (1000 Packs)	5 L (1000 Packs)	5 L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	30-11-2022	30-11-2022	30-11-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
Reference of previous approval of applications with stability study data of the firm (if any)			
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Tobramycin: Copy of DML# Chongqing 20150039 issued by NMPA dated: 22-12-2022 and valid till 15-11-2025 submitted Dexamethasone: Firm has submitted copy of GMP certificate # ZJ20190093 issued by NDMA valid till 04-08-2024.		
Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between Medevo (Pvt) Limited and Innovotek pharmaceuticals submitted. Firm has submitted copy of Clearance certificate # specifying Invoice #PHL206738, dated; 10-03-2020 specifying Tobramycin base Batch #.08191203-U Firm has submitted copy of Commercial Invoice # XJWH1611161PPK, attested by DRAP (Lahore)specifying Dexamethason Batch #. X5-161102		
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.		
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system		
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
Evaluation by PEC (No.IV):			

S.No	Section	Shortcoming	Reply
1.	1.3.5	Evidence of separate dispensing booths for steroids.	Inspection report is attached.
2.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) shall be submitted for both Tobramycin and dexamethasone.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both drug substance(s) Tobramycin and dexamethasone is submitted.
3.	3.2.S.4.4	Submitted COA of Dexamethasone show expiry on 05-11-2022 than how testing on 16-11-2022 can be conducted.	Revised COA is submitted.
4.	3.2.P.1	Innovator product add Sulfuric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.	Sodium hydroxide is used to adjust the pH and evident from batch manufacturing record.
5.	3.2.P.5.2	Detailed analytical procedures used for testing the drug product shall be provided.	Detailed analytical procedures used for testing of the drug product are submitted.
6.	3.2.P.5.3	Submit analytical method verification report	Analytical method verification report is submitted.
7.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided for both Tobramycin and dexamethasone.	COA of primary / secondary reference standard for both Tobramycin and dexamethasone are submitted.
8.	3.2.P.8	Documents for the procurement of API with approval from DRAP and agreement for loan of material for dexamethasone	Documents for the procurement of API is submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

187	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.**
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking Id: 42M-8WQ-4XDN Application No. 1463 dated 11-03-2024
	Details of fee submitted	PKR 30,000/- : Deposit slip # **857795793779**
	The proposed proprietary name / brand name	Surgisys Eye Drop (0.4 % Polyethylene Glycol 400 and 0.3% Propylene Glycol Ophthalmic Solution)

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Polyethylene Glycol 400 …. 4 mg Propylene Glycol …….3 mg
	Pharmacotherapeutic Group of (API)	Lubricant Eye Drops
	Reference to Finished product specifications	Innovator's specs

EVALUATION OF DATA	
GMP status of the firm	New DML issued dated: 08-11-2022
Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section
Proposed Pack size	15ml
Proposed unit price	As per SRO
The status in reference regulatory authorities	**SYSTANE LUBRICANT** by Alcon Laboratories, Inc of (OTC product in USFDA)
For generic drugs (me-too status)	Systane by M/s Alcon Laboratories, Inc.Reg # 044834
Name and address of API manufacturer.	**PROPYLENE GLYCOL:** Shandong Shida Shenghua Chemical 198, Tongxing Road, Kenli District, Dongying City, Shandong-China **Polyethylene glycol:** Anhui Eapearl Chemical Co.Ltd. Economic Development Zone TOngling City, Anhui Province CHINA
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Propylene Glycol: Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions. Polyethylene Glycol 400 : Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Systane ophthalmic Solution Manufactured by Alcon Laboratories.
Analytical method validation/verification of product	

STABILITY STUDY DATA			
API Lot No.	Propylene Glycol: Polyethylene Glycol 400 : EP20230414H		
Description of Pack (Container closure system)	HDPE bottle		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	SYS-TRIAL001	SYS-TRIAL002	SYS-TRIAL003
Batch Size	15 L (1000 Packs)	15 L (1000 Packs)	15 L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022

Date of Initiation			
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
Reference of previous approval of applications with stability study data of the firm (if any)			
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			
Documents for the procurement of API with approval from DRAP (in case of import).			
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.		
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system		
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		

Evaluation by PEC (No.IV):

S.No	Section	Shortcoming
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required for both Propylene Glycol and Polyethylene Glycol
3.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required for both Propylene Glycol and Polyethylene Glycol
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) shall be submitted for both Propylene Glycol and Polyethylene Glycol
5.	3.2.S.4.4	Submit COA of both drug substances by drug substance manufacturer and drug product manufacturer with batch No used during product development and stability studies
6.	3.2.P.1	Reference product add hydrochloric acid and/or sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.
7.	3.2.P.5.1	Submit specification of applied product.
8.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided for both Propylene Glycol and Polyethylene Glycol.
9.	3.2.P.8	• Documents for the procurement of API with approval from DRAP • Initiation date of stability studies not mentioned

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

b. New/Additional section(s)

M/s Kaizen Pharmaceuticals Pvt Ltd **(Additional New Section)**
CLB in its 280th meeting held on 26th & 27th April 2021, has approved the following 01 additional sections of M/s Kaizen Pharmaceuticals Pvt Ltd.

1.Soft Gelatin Capsule (General)

188.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP dated 09-09-2021 on the basis of evaluation conducted on 03-09-2021 and valid for 2 years.
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional sectio dated 18-05-2021 specifying Soft Gelatin capsule General.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16591 dated 04-07-2023
	Details of fee submitted	PKR 75,000/- Deposit Slip# 65329815660
	The proposed proprietary name / brand name	**Invital-D 50,000 IU Soft Gelatin Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains: 1.25mg of Cholecalciferol (40MIU/G) Eq. to Cholecalciferol…….50,000 IU
	Pharmacotherapeutic Group of (API)	Vitamin D3 and analogue, Cholecalciferol
	Pharmaceutical form of applied drug	Red Shiny Oval shaped Soft Gelatin Capsule filled with transparent solution.
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	InVita D3 50,000 IU soft capsules is marketed by Consilient Health Limited of MHRA approved).
	For generic drugs (me-too status)	Not available in Pakistan.
	Name and address of API manufacturer.	M/s Fermenta Biotech Limited Plot No. Z-109 B & C, SEZ-II., Dahej, Tal-Vagra, City Dahej, District Bharuch Gujrat state, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description

		of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 5°C ± 2°C % for 36 months Accelerated: 25°C ± 2°C / 60% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Banferol soft Gelatin capsule 50000IU manufactured by Angelini Pharma Spain by performing quality tests (Physical appearance, colour, Assay)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Fermenta Biotech Limited Plot No. Z-109 B & C, SEZ-II., Dahej, Tal-Vagra, City Dahej, District Bharuch Gujrat state, India.		
API Lot No.	CLC0420170		
Description of Pack (Container closure system)	Alu-Pvdc Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1000 Capsule	1000 Capsule	1000 Capsule
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	12-2022	12-2022	12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No. 23074378) issued by Food & Drug Control Administration Gujrat State India issued dated:05-07-2023 and valid till 04-07-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 6, [License to Import Drug(s) for Clinical Trial, Examination, Test or Analysis no. K-1110946089473 issued on 14/10/2022 by Drug Regulatory Authority of Pakistan, Karachi valid till 13/10/2024 specifying Cholecalciferol 40M IU/g was provided.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Copy of BMR is submitted.
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Copy of drug substance specification are submitted
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
4.	3.2.S.4.4	Which specifications are followed by drug product manufacturer for drug substance.	We have followed British Pharmacopoeia Specifications for testing of Drug substance
5.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary / secondary reference standard submitted.
6.	3.2.P.8	• Commercial Invoice for the procurement of API with approval from DRAP. • Submit 6th month stability studies data as Submitted stability studies data of 3 moths.	• Firm submitted form 6 (for clinical Trial examination test or analysis) No # K-1110946089473 dated: 14-10-2022 specifying Cholecalciferol from M/s Fermenta Biotech Limited. • Submitted.

Decision: Approved.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
189.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd.** **E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP dated 09-09-2021 on the basis of evaluation conducted on 03-09-2021 and valid for 2 years..
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional sectio dated 18-05-2021 specifying Soft Gelatin capsule General.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24898 dated 12-10-2023
	Details of fee submitted	PKR 75,000/- Deposit Slip# 1855735727
	The proposed proprietary name / brand name	**Invital-D 100,000 IU SG Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains: Cholecalciferol …….100,000 IU
	Pharmacotherapeutic Group of (API)	Vitamin D3 and analogue, Cholecalciferol
	Pharmaceutical form of applied drug	Red Shiny Oval shaped Soft Gelatin Capsule filled with transparent solution.
	Reference to Finished product specifications	USP
	Proposed Pack size	1's,2's, 3's & 6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	KIPOS 100 000 IU soft capsules by Iprad Pharma Laboratories of ANSM approved.
	For generic drugs (me-too status)	Not available in Pakistan.
	Name and address of API manufacturer.	M/s Fermenta Biotech Limited Plot No. Z-109 B & C, SEZ-II., Dahej, Tal-Vagra, City Dahej, District Bharuch Gujrat state, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications,

		analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 5°C ± 2°C % for 36 months Accelerated: 25°C ± 2°C / 60% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Banferol soft Gelatin capsule 100000IU manufactured by Consilient Health Ireland by performing quality tests (Physical appearance, color, Assay)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Fermenta Biotech Limited Plot No. Z-109 B & C, SEZ-II., Dahej, Tal-Vagra, City Dahej, District Bharuch Gujrat state, India.		
API Lot No.	CLC0420170		
Description of Pack (Container closure system)	Alu-Pvdc Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1000 Capsule	1000 Capsule	1000 Capsule
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	01-2023	01-2023	01-2023
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No. 23074378) issued by Food & Drug Control Administration Gujrat State India issued dated:05-07-2023 and valid till 04-07-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 6, [License to Import Drug(s) for Clinical Trial, Examination, Test or Analysis no. K-1110946089473 issued on 14/10/2022 by Drug Regulatory Authority of Pakistan, Karachi valid till 13/10/2024 specifying Cholecalciferol 40M IU/g was provided.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Copy of BMR is submitted.
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Copy of drug substance specification are submitted
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
4.	3.2.S.4.4	Which specifications are followed by drug product manufacturer for drug substance.	We have followed British Pharmacopoeia Specifications for testing of Drug substance
5.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary / secondary reference standard submitted.
6.	3.2.P.8	Commercial Invoice for the procurement of API with approval from DRAP.	Firm submitted form 6 (for clinical Trial examination test or analysis) No # K-1110946089473 dated: 14-10-2022 specifying Cholecalciferol from M/s Fermenta Biotech Limited.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
190.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP dated 09-09-2021 on the basis of evaluation conducted on 03-09-2021 and valid for 2 years..
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional sectio dated 18-05-2021 specifying Soft Gelatin capsule General.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24896 dated 12-10-2023
	Details of fee submitted	PKR 75,000/- Deposit Slip# 84660436
	The proposed proprietary name / brand name	**Invital-D 20,000 IU SG Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains: Cholecalciferol …….20,000 IU
	Pharmacotherapeutic Group of (API)	Vitamin D3 and analogue, Cholecalciferol
	Pharmaceutical form of applied drug	Red Shiny Oval shaped Soft Gelatin Capsule filled with transparent solution.
	Reference to Finished product specifications	USP
	Proposed Pack size	4's, 10's,20's, & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Aviticol 20,000 IU soft capsules is marketed Colonis Pharma Limited of MHRA approved.
	For generic drugs (me-too status)	Not available in Pakistan.
	Name and address of API manufacturer.	M/s Fermenta Biotech Limited Plot No. Z-109 B & C, SEZ-II., Dahej, Tal-Vagra, City Dahej, District Bharuch Gujrat state, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 5°C ± 2°C % for 36 months Accelerated: 25°C ± 2°C / 60% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Lundeos soft Gelatin capsule 20000IU of Theramex Healthcare Spain by performing quality tests (Physical appearance, colour, Assay)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Fermenta Biotech Limited Plot No. Z-109 B & C, SEZ-II., Dahej, Tal-Vagra, City Dahej, District Bharuch Gujrat state, India.		
API Lot No.	CLC0420170		
Description of Pack (Container closure system)	Alu-Pvdc Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1000 Capsule	1000 Capsule	1000 Capsule
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	01-2023	01-2023	01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No. 23074378) issued by Food & Drug Control Administration Gujrat State India issued dated:05-07-2023 and valid till 04-07-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 6, [License to Import Drug(s) for Clinical Trial, Examination, Test or Analysis no. K-1110946089473 issued on 14/10/2022 by Drug Regulatory Authority of Pakistan, Karachi valid till 13/10/2024 specifying Cholecalciferol 40M IU/g was provided.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Copy of BMR is submitted.
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Copy of drug substance specification are submitted
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
4.	3.2.S.4.4	Which specifications are followed by drug product manufacturer for drug substance.	We have followed British Pharmacopoeia Specifications for testing of Drug substance
5.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary / secondary reference standard submitted.
6.	3.2.P.8	Commercial Invoice for the procurement of API with approval from DRAP.	Firm submitted form 6 (for clinical Trial examination test or analysis) No # K-1110946089473 dated: 14-10-2022 specifying Cholecalciferol from M/s Fermenta Biotech Limited.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

191.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.

	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP dated 09-09-2021 on the basis of evaluation conducted on 03-09-2021 and valid for 2 years..
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional sectio dated 18-05-2021 specifying Soft Gelatin capsule General.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24897 dated 12-10-2023
	Details of fee submitted	PKR 75,000/- Deposit Slip# 8442030998
	The proposed proprietary name / brand name	**Invital-D 25,000 IU SG Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains: Cholecalciferol …….25,000 IU
	Pharmacotherapeutic Group of (API)	Vitamin D3 and analogue, Cholecalciferol
	Pharmaceutical form of applied drug	Red Shiny Oval shaped Soft Gelatin Capsule filled with transparent solution.
	Reference to Finished product specifications	USP
	Proposed Pack size	4's, 12's, 10's,20's, & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	InVita D3 25,000 IU soft capsules is marketed by Consilient Health Limited of MHRA approved.
	For generic drugs (me-too status)	Not available in Pakistan.
	Name and address of API manufacturer.	M/s Fermenta Biotech Limited Plot No. Z-109 B & C, SEZ-II., Dahej, Tal-Vagra, City Dahej, District Bharuch Gujrat state, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis

		and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 5°C ± 2°C % for 36 months Accelerated: 25°C ± 2°C / 60% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Banferol soft Gelatin capsule 250000IU manufactured by Angelini Pharma spain by performing quality tests (Physical appearance, colour, Assay)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Fermenta Biotech Limited Plot No. Z-109 B & C, SEZ-II., Dahej, Tal-Vagra, City Dahej, District Bharuch Gujrat state, India.		
API Lot No.	CLC0420170		
Description of Pack (Container closure system)	Alu-Pvdc Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1000 Capsule	1000 Capsule	1000 Capsule
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	01-2023	01-2023	01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No. 23074378) issued by Food & Drug Control Administration Gujrat State India issued dated:05-07-2023 and valid till 04-07-2026.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 6, [License to Import Drug(s) for Clinical Trial, Examination, Test or Analysis no. K-1110946089473 issued on 14/10/2022 by Drug Regulatory Authority of Pakistan, Karachi valid till 13/10/2024 specifying Cholecalciferol 40M IU/g was provided.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Copy of BMR is submitted.
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Copy of drug substance specification are submitted
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
4.	3.2.S.4.4	Which specifications are followed by drug product manufacturer for drug substance.	We have followed British Pharmacopoeia Specifications for testing of Drug substance
5.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary / secondary reference standard submitted.
6.	3.2.P.8	Commercial Invoice for the procurement of API with approval from DRAP.	Firm submitted form 6 (for clinical Trial examination test or analysis) No # K-1110946089473 dated: 14-10-2022 specifying Cholecalciferol from M/s Fermenta Biotech Limited.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

192.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd.

		E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP dated 09-09-2021 on the basis of evaluation conducted on 03-09-2021 and valid for 2 years..
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional sectio dated 18-05-2021 specifying Soft Gelatin capsule General.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24894 dated 12-10-2023
	Details of fee submitted	PKR 75,000/- Deposit Slip# 39820225947
	The proposed proprietary name / brand name	**Invital-D 1,000 IU SG Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains: Cholecalciferol …….1,000 IU
	Pharmacotherapeutic Group of (API)	Vitamin D3 and analogue, Cholecalciferol
	Pharmaceutical form of applied drug	Red Shiny Oval shaped Soft Gelatin Capsule filled with transparent solution.
	Reference to Finished product specifications	USP
	Proposed Pack size	30's, & 60's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	UVECAPS 1,000 IU soft capsules by CRINEX Laboratories of ANSM approved.
	For generic drugs (me-too status)	Not available in Pakistan.
	Name and address of API manufacturer.	M/s Fermenta Biotech Limited Plot No. Z-109 B & C, SEZ-II., Dahej, Tal-Vagra, City Dahej, District Bharuch Gujrat state, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 5˚C ± 2˚C % for 36 months Accelerated: 25˚C ± 2˚C / 60% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Lundeos soft Gelatin capsule 1000IU manufactured by Theramax UK by performing quality tests (Physical appearance, colour, Assay)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Fermenta Biotech Limited Plot No. Z-109 B & C, SEZ-II., Dahej, Tal-Vagra, City Dahej, District Bharuch Gujrat state, India.		
API Lot No.	CLC0420170		
Description of Pack (Container closure system)	Alu-Pvdc Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1000 Capsule	1000 Capsule	1000 Capsule
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	01-2023	01-2023	01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No. 23074378) issued by Food & Drug Control Administration Gujrat State India issued dated:05-07-2023 and valid till 04-07-2026.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 6, [License to Import Drug(s) for Clinical Trial, Examination, Test or Analysis no. K-1110946089473 issued on 14/10/2022 by Drug Regulatory Authority of Pakistan, Karachi valid till 13/10/2024 specifying Cholecalciferol 40M IU/g was provided.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Copy of BMR is submitted.
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Copy of drug substance specification are submitted
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
4.	3.2.S.4.4	Which specifications are followed by drug product manufacturer for drug substance.	We have followed British Pharmacopoeia Specifications for testing of Drug substance
5.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary / secondary reference standard submitted.
6.	3.2.P.8	Commercial Invoice for the procurement of API with approval from DRAP.	Firm submitted form 6 (for clinical Trial examination test or analysis) No # K-1110946089473 dated: 14-10-2022 specifying Cholecalciferol from M/s Fermenta Biotech Limited.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

193.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd.

		E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP dated 09-09-2021 on the basis of evaluation conducted on 03-09-2021 and valid for 2 years..
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional sectio dated 18-05-2021 specifying Soft Gelatin capsule General.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24895 dated 12-10-2023
	Details of fee submitted	PKR 75,000/- Deposit Slip# 11800986706
	The proposed proprietary name / brand name	**Invital-D 5,600 IU SG Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains: Cholecalciferol …….5600 IU
	Pharmacotherapeutic Group of (API)	Vitamin D3 and analogue, Cholecalciferol
	Pharmaceutical form of applied drug	Red Shiny Oval shaped Soft Gelatin Capsule filled with transparent solution.
	Reference to Finished product specifications	USP
	Proposed Pack size	4’s, 12’s, 10’s,20’s, & 30’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Benferol 5600 IU soft capsules by Consilient Health Ltd of Noweign Medicine Agency approved.
	For generic drugs (me-too status)	Not available in Pakistan.
	Name and address of API manufacturer.	M/s Fermenta Biotech Limited Plot No. Z-109 B & C, SEZ-II., Dahej, Tal-Vagra, City Dahej, District Bharuch Gujrat state, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility’s, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 5°C ± 2°C % for 36 months Accelerated: 25°C ± 2°C / 60% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Banferol soft Gelatin capsule 6500IU manufactured by Consilient Health Ireland by performing quality tests (Physical appearance, color, Assay)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Fermenta Biotech Limited Plot No. Z-109 B & C, SEZ-II., Dahej, Tal-Vagra, City Dahej, District Bharuch Gujrat state, India.		
API Lot No.	CLC0420170		
Description of Pack (Container closure system)	Alu-Pvdc Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1000 Capsule	1000 Capsule	1000 Capsule
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	01-2023	01-2023	01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No. 23074378) issued by Food & Drug Control Administration Gujrat State India issued dated:05-07-2023 and valid till 04-07-2026.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 6, [License to Import Drug(s) for Clinical Trial, Examination, Test or Analysis no. K-1110946089473 issued on 14/10/2022 by Drug Regulatory Authority of Pakistan, Karachi valid till 13/10/2024 specifying Cholecalciferol 40M IU/g was provided.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Copy of BMR is submitted.
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Copy of drug substance specification are submitted
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
4.	3.2.S.4.4	Which specifications are followed by drug product manufacturer for drug substance.	We have followed British Pharmacopoeia Specifications for testing of Drug substance
5.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary / secondary reference standard submitted.
6.	3.2.P.8	Commercial Invoice for the procurement of API with approval from DRAP.	Firm submitted form 6 (for clinical Trial examination test or analysis) No # K-1110946089473 dated: 14-10-2022 specifying Cholecalciferol from M/s Fermenta Biotech Limited.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

194.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd.

		E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP dated 09-09-2021 on the basis of evaluation conducted on 03-09-2021 and valid for 2 years..
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional sectio dated 18-05-2021 specifying Soft Gelatin capsule General.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24893 dated 12-10-2023
	Details of fee submitted	PKR 75,000/- Deposit Slip# 3651671804
	The proposed proprietary name / brand name	**Invital-D 800 IU SG Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains: Cholecalciferol …….800 IU
	Pharmacotherapeutic Group of (API)	Vitamin D3 and analogue, Cholecalciferol
	Pharmaceutical form of applied drug	Red Shiny Oval shaped Soft Gelatin Capsule filled with transparent solution.
	Reference to Finished product specifications	USP
	Proposed Pack size	30's, & 60's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	InVita D3 800 IU soft capsules by Consilient Health Ltd of MHRA approved.
	For generic drugs (me-too status)	Not available in Pakistan.
	Name and address of API manufacturer.	M/s Fermenta Biotech Limited Plot No. Z-109 B & C, SEZ-II., Dahej, Tal-Vagra, City Dahej, District Bharuch Gujrat state, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 5°C ± 2°C % for 36 months Accelerated: 25°C ± 2°C / 60% ± 5% for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Banferol soft Gelatin capsule 800IU manufactured by Goodlife pharma Netherland by performing quality tests (Physical appearance, colour, Assay)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Fermenta Biotech Limited Plot No. Z-109 B & C, SEZ-II., Dahej, Tal-Vagra, City Dahej, District Bharuch Gujrat state, India.		
API Lot No.	CLC0420170		
Description of Pack (Container closure system)	Alu-Pvdc Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1000 Capsule	1000 Capsule	1000 Capsule
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	01-2023	01-2023	01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has also submitted copy of GMP certificate of the firm (No. 23074378) issued by Food & Drug Control Administration Gujrat State India issued dated:05-07-2023 and valid till 04-07-2026.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 6, [License to Import Drug(s) for Clinical Trial, Examination, Test or Analysis no. K-1110946089473 issued on 14/10/2022 by Drug Regulatory Authority of Pakistan, Karachi valid till 13/10/2024 specifying Cholecalciferol 40M IU/g was provided.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Copy of BMR is submitted.
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Copy of drug substance specification are submitted
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
4.	3.2.S.4.4	Which specifications are followed by drug product manufacturer for drug substance.	We have followed British Pharmacopoeia Specifications for testing of Drug substance
5.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary / secondary reference standard submitted.
6.	3.2.P.8	Commercial Invoice for the procurement of API with approval from DRAP.	Firm submitted form 6 (for clinical Trial examination test or analysis) No # K-1110946089473 dated: 14-10-2022 specifying Cholecalciferol from M/s Fermenta Biotech Limited.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

M/s Siam Pharmaceutical **(Additional New Section)**
CLB in its 285th meeting held on 17th & 18th March 2022, has approved the following 02 additional sections of M/s Siam Pharmaceutical.

1. Sachet Section (General).
2. Finished Good store (Revised)

195.	Name, address of Applicant / Marketing Authorization Holder	M/s Siam Pharmaceutical Plot # 217, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Siam Pharmaceutical Plot # 217, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Tracking Id: L92-QHH-A7E4 Application No. 2425 dated 19-03-2024
	Details of fee submitted	PKR 30,000/- : Deposit slip # **0388857162**
	The proposed proprietary name / brand name	Omitid Sachet 20 mg/1680 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains: Omeprazole .....20mg Sodium bicarbonate……1680 mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	Innovator's Specifications

EVALUATION OF DATA

GMP status of the firm	
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional sections dated 26-05-2022. specifying Sachet Section (General).
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Zegerid for Immediate Release Oral Suspension by Santarus, Inc of (USFDA Approved)
For generic drugs (me-too status)	Risek Insta for Immediate Release Oral Suspension. by Getz Pharma.
Name and address of API manufacturer.	Omeprazole: M/s Everest Organics limited. Address: Aroor Village, Sadasivpet Mandal, Sangareddy Dist. Telangana. Sodium bicarbonate : M/s United Chem Address: 18-Warlley Moor Lane Leeds West Workshire LS 12 4HX
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Zegerid POWDER FOR ORAL SUSPENSION By Santarus Inc.

	Firm has submitted CDP results of their product against the innovator's Zegerid POWDER FOR ORAL SUSPENSION By Santarus Inc.		
Analytical method validation/verification of product			
STABILITY STUDY DATA			
API Lot No.	Omeprazole: OME/E-143/21 Sodium bicarbonate: 547908		
Description of Pack (Container closure system)	Aluminium foil sachet Packed in packing box		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	2000 Sachet	2000 Sachet	2000 Sachet
Manufacturing Date	06-2023	06-2023	06-2023
Date of Initiation	06-06-2023	06-06-2023	06-06-2023
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
Reference of previous approval of applications with stability study data of the firm (if any)	.		
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Omeprazole :Firm has submitted copy of GMP certificate issued by Drug Control Administration Govt of Telangna India valid till 08-08-2022.		
Documents for the procurement of API with approval from DRAP (in case of import).			
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.		
Compliance Record of HPLC software 21CFR & audit trail reports on product testing			
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
Evaluation by PEC (No. IV):			
USP monograph for Omeprazole Oral Suspension: Omeprazole Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of omeprazole ($C_{17}H_{19}N_3O_3S$). Prepare Omeprazole Oral Suspension 2 mg/mL as follows (see Pharmaceutical Compounding—Nonsterile Preparations) Calculate the required quantity of each ingredient for the total amount to be prepared. Empty the required number of packets in a suitable mortar. Add Purified Water in small portions, and triturate to make a smooth paste. Add increasing volumes of Purified Water to make an omeprazole liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough Purified Water to bring to final volume, and mix well.			

S.No	Section	Shortcoming
5.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted
6.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin for both Omeprazole and sodium bicarbonate.
7.	2.3.R.1.1	In BMR USP specifications are mentioned while applied on Innovator specifications.
8.	3.2.S.4.4	In COA's of drug substance (Sodium bicarbonate) specifications claimed are USP while limits for assay are NLT 99.0% & NMT 101.0% which is not as per USP monograph. Clarifications is required.
9.	3.2.S.7	Submit accelerated and Real time Stability studies of Omeprazole and sodium bicarbonate for 03 batches as per zone IV condition.
10.	3.2.P.2.6	Compatibility studies for the dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product
11.	3.2.P.5.1	Innovator product specification for dissolution is Q in 15 minutes while yours specification for dissolution is NLT 75% (Q) of the labelled amount in 30 minutes. Clarification is required.
12.	3.2.P.5.3	• Submit complete analytical validation for Omeprazole in drug product. • Analytical method validation for sodium bicarbonate not submitted.
13.	3.2.P.8	• Documents for the procurement of API with approval from DRAP. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing

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

Agenda of Evaluator PEC-IX

Routine cases on Form-5F

196.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s City Pharmaceutical Laboratories, Plot no. 12-A, 1-5, Sector 5, New Survey No. 276, Korangi Industrial Area, Karachi. (DML No. 000723)**
	Name, address of Manufacturing site.	M/s City Pharmaceutical Laboratories, Plot no. 12-A, 1-5, Sector 5, New Survey No. 276, Korangi Industrial Area, Karachi. DML No. 000723
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of certificate No. 89/2022-DRAP(K) dated 23.06.2022 valid till 28.12.2023, issued by DRAP Karachi is submitted.
	Evidence of approval of manufacturing facility	Copy of layout approval letter is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23833 dated 23.08.2022
	Details of fee submitted	**PKR 30,000/-** Slip No. 9655300162 dated 06.06.2022

	The proposed proprietary name / brand name	**CIXIM 200mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Cefixime Trihydrate eq. to Cefixime…200mg
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins ATC Code: J01DD08
	Pharmaceutical form of applied drug	Hard gelatin capsule.
	Reference to Finished product specifications	**Manufacturer Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SUPRAX 200 mg CAPSULE by SANOFI Aventis Spain Approved
	For generic drugs (me-too status)	Cefiget 200 mg Capsule by M/s GETZ Pharma
	Name and address of API manufacturer.	M/s Saakh Pharma (Pvt.) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karachi. Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 21CF10237
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. 19CF10001, 19CF10036, 19CF10084
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative	**Test product:** Cixim 200mg Capsule Batch No.

	Dissolution Profile	TY-001. **Reference product:** Cefspan 200mg Capsule, Batch No. 7C602, manufactured by M/s Barrett Hodgson. **Tests done:** Identification, Water content, Dissolution, Assay **CDP;** **pH 1.2:** More than 85% in 15 min **pH 4.5:** More than 85% in 15 min **pH 6.8:** More than 85% in 15 min
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Saakh Pharma (Pvt.) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karachi. Pakistan.		
API Lot No.	21CF10237		
Description of Pack (Container closure system)	5's Capsules in Alu Alu Blisters, packed in card board unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 Capsules	2000 Capsules	2000 Capsules
Manufacturing Date	11.2021	11.2021	11.2021
Date of Initiation	01.12.2021	01.12.2021	01.12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 83/2020-DRAP (K) valid till 17.06.2022 issued by DRAP Karachi is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Cefixime compacted** Batch No.: 21CF10237 Mfg date: - Retest: - Quantity: 2kg Invoice No.: CFX/2021/4210 Invoice date: 26.11.2021 Cleared by: Purchased from Saakh Pharma Pakistan.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	-	Copy of Section approval letter is required.	The firm vide letter No. nil dated 18.01.2024 has submitted copy of layout approval letter No. 2-2/2008-Lic dated 25.07.2009 wherein in Cephalosporin capsule section is mentioned. Copy of GMP certificate submitted also mentions the same section
2.	-	Copy of latest GMP certificate or inspection report is required.	Copy of certificate No. 89/2022-DRAP(K) dated 23.06.2022 valid till 28.12.2023, issued by DRAP Karachi is submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

197.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000417
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 3-16/2018-Addl. Dir. (QA&LT)-1 dated 04.01.2022 valid till 02.01.2024 issued by DRAP Islamabad is submitted.
	Evidence of approval of manufacturing facility	Copy of section approval letter No. 1-1/96-Lic(Vol-II) dated 13.06.2017 is submitted. Tablet Section (general)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23674 dated 22.08.2022
	Details of fee submitted	**PKR 30,000/-** Slip No. 4478157697 dated 18.08.2022
	The proposed proprietary name / brand name	**Deglu-Met XR 5mg/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Dapagliflozin as propendiol monohydrate..5mg Metformin HCl (extended release)……500mg

	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs ATC Code: A10BD15
	Pharmaceutical form of applied drug	Orange colour, oblong shaped, dapagliflozin (IR) Metformin (XR) film coated tablet.
	Reference to Finished product specifications	**Innovator Specifications**
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XIGDUO XR 5mg;500mg Tablet USFDA Approved.
	For generic drugs (me-too status)	Dapa-Met XR Tablet 5/500mg Reg No. 110358 M/s Hilton Pharma (Pvt) Limited.
	Name and address of API manufacturer.	**Dapagliflozin;** M/s Fuxin Long Rui Pharmaceutical Co. Ltd. Flouride Industrial Park, Fumeng (Yi Ma tu), Fuxin City, Liaoning Province China. **Metformin HCl;** M/s Aarti Drugs Limited, Plot No. 211-213, Road No. 2, G.I.D.C., Sarigram Dist. Valsad, Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Dapagliflozin;** DG-20190327-D01-DG06-05 (2001R0056) **Metformin HCl;** MEF/10030953 (2008R0046)
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. (48 months for metformin HCl, rest of the conditions are same for both drug sisbtances.) **Dapagliflozin;** 160108, 160124, 160220. **Metformin HCl;** MEF/1410027, MEF/1410028, MEF/1410029.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical

		development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Deglu-Met XR 5/500 batch ST21H011. **Reference product:** Xigduo XR 5/500mg Tablet, Batch No. MC0087 manufactured by M/s AstraZeneca Pharmaceuticals AB Sweden. **Tests done:** Physical Attributes, Identification, Assay, content uniformity. **CDP:** **pH 1.2:** 81.68, 73.65 **pH 4.5:** 91.5, 69.19 **pH 6.8:** 92.3, 78.02
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Dapagliflozin;** M/s Fuxin Long Rui Pharmaceutical Co. Ltd. Flouride Industrial Park, Fumeng (Yi Ma tu), Fuxin City, Liaoning Province China. **Metformin HCl;** M/s Aarti Drugs Limited, Plot No. 211-213, Road No. 2, G.I.D.C., Sarigram Dist. Valsad, Gujrat India.		
API Lot No.	**Dapagliflozin;** DG-20190327-D01-DG06-05 (2001R0056) **Metformin HCl;** MEF/10030953 (2008R0046)		
Description of Pack (Container closure system)	Orange colour, oblong shaped film coated tablets, in Alu-Alu blister of 7's packed in UC of 14's.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST21H011	ST21H012	-
Batch Size	5000 tablets	5000 tablets	-
Manufacturing Date	08.2021	08.2021	-
Date of Initiation	28.08.2021	28.08.2021	-
No. of Batches	2		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin;** M/s Fuxin Long Rui Pharmaceutical Co. Ltd. Copy of License No. Liao20150233 issued by FDA Liaoning China, valid till 20.12.2022 is submitted. **Metformin HCl;** M/s Aarti Drugs Limited.

		Copy of GMP certificate No. 20031933 valid till 19.03.2023 issued by Food and Drug Control Administration, Gujrat State India is Submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin;** Batch No.: DG-20190327-D01-DG06-05 Mfg date: 05.10.2019 EXP: 04.10.2021 Quantity: 1.5kg Invoice No.: HN1912054-H Invoice date: 05.12.2019 Cleared by: AD I&E DRAP Islamabad. **Metformin HCl;** Batch No.: MEF/10030953 Mfg date: 03.2020 EXP: 02.2025 Quantity: 1000Kg Invoice No.: EXP/302/21-21 Invoice date: 15.05.2020 Cleared by: AD I&E DRAP Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

198.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000417
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 3-16/2018-Addl. Dir. (QA&LT)-1 dated 04.01.2022 valid till 02.01.2024 issued by DRAP Islamabad is submitted.
	Evidence of approval of manufacturing facility	Copy of section approval letter No. 1-1/96-Lic(Vol-II) dated 13.06.2017 is submitted. Tablet Section (general)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23676 dated 22.08.2022
	Details of fee submitted	**PKR 30,000/-** Slip No. 7405864491 dated 19.08.2022
	The proposed proprietary name / brand name	**Deglu-Met XR 5mg/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Dapagliflozin as propendiol monohydrate..5mg Metformin HCl (extended release)……1000mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs ATC Code: A10BD15
	Pharmaceutical form of applied drug	Pink to dark pink colour, oblong shaped, dapagliflozin (IR) Metformin (XR) film coated tablet.
	Reference to Finished product specifications	**Innovator Specifications**
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XIGDUO XR 5mg;1g Tablet USFDA Approved.
	For generic drugs (me-too status)	Dapa-Met XR Tablet 5/1000mg Reg No. 105283 M/s Hilton Pharma (Pvt) Limited.
	Name and address of API manufacturer.	**Dapagliflozin;** M/s Fuxin Long Rui Pharmaceutical Co. Ltd. Flouride Industrial Park, Fumeng (Yi Ma tu), Fuxin City, Liaoning Province China. **Metformin HCl;** M/s Aarti Drugs Limited, Plot No. 211-213, Road No. 2, G.I.D.C., Sarigram Dist. Valsad, Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Dapagliflozin;** DG-20190327-D01-DG06-05 (2001R0056) **Metformin HCl;** MEF/10030953 (2008R0046)
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches of

	(Conditions & duration of Stability studies)	drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. (48 months for metformin HCl, rest of the conditions are same for both drug sisbtances.) **Dapagliflozin;** 160108, 160124, 160220. **Metformin HCl;** MEF/1410027, MEF/1410028, MEF/1410029.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Deglu-Met XR 5/1000 batch ST21H007. **Reference product:** Xigduo XR 5/1000mg Tablet, Batch No. LP0226 manufactured by M/s AstraZeneca Pharmaceuticals AB Sweden. **Tests done:** Physical Attributes, Identification, Assay, content uniformity. **CDP:** **pH 1.2:** 91.66, 71.27 **pH 4.5:** 96.63, 77.51 **pH 6.8:** 98.12, 84.39
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Dapagliflozin;** M/s Fuxin Long Rui Pharmaceutical Co. Ltd. Flouride Industrial Park, Fumeng (Yi Ma tu), Fuxin City, Liaoning Province China. **Metformin HCl;** M/s Aarti Drugs Limited, Plot No. 211-213, Road No. 2, G.I.D.C., Sarigram Dist. Valsad, Gujrat India.		
API Lot No.	**Dapagliflozin;** DG-20190327-D01-DG06-05 (2001R0056) **Metformin HCl;** MEF/10030953 (2008R0046)		
Description of Pack (Container closure system)	Pink to dark pink colour, oblong shaped film coated tablets, in Alu-Alu blister of 7's packed in UC of 14's.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST21H007	ST21H008	-
Batch Size	5000 tablets	5000 tablets	-
Manufacturing Date	08.2021	08.2021	-

Date of Initiation	22.09.2021	22.09.2021	-
No. of Batches	2		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin;** M/s Fuxin Long Rui Pharmaceutical Co. Ltd. Copy of License No. Liao20150233 issued by FDA Liaoning China, valid till 20.12.2022 is submitted. **Metformin HCl;** M/s Aarti Drugs Limited. Copy of GMP certificate No. 20031933 valid till 19.03.2023 issued by Food and Drug Control Administration, Gujrat State India is Submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin;** Batch No.: DG-20190327-D01-DG06-05 Mfg date: 05.10.2019 EXP: 04.10.2021 Quantity: 1.5kg Invoice No.: HN1912054-H Invoice date: 05.12.2019 Cleared by: AD I&E DRAP Islamabad. **Metformin HCl;** Batch No.: MEF/10030953 Mfg date: 03.2020 EXP: 02.2025 Quantity: 1000Kg Invoice No.: EXP/302/21-21 Invoice date: 15.05.2020 Cleared by: AD I&E DRAP Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

199.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000417
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 3-16/2018-Addl. Dir. (QA&LT)-1 dated 04.01.2022 valid till 02.01.2024 issued by DRAP Islamabad is submitted.
	Evidence of approval of manufacturing facility	Copy of section approval letter No. 1-1/96-Lic(Vol-II) dated 13.06.2017 is submitted. Tablet Section (general)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23675 dated 22.08.2022
	Details of fee submitted	**PKR 30,000/-** Slip No. 7414279331 dated 19.08.2022
	The proposed proprietary name / brand name	**Deglu-Met XR 10mg/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Dapagliflozin as propendiol monohydrate..10mg Metformin HCl (extended release)……500mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs ATC Code: A10BD15
	Pharmaceutical form of applied drug	Pink to dark pink colour, oblong shaped, dapagliflozin (IR) Metformin (XR) film coated tablet.
	Reference to Finished product specifications	**Innovator Specifications**
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XIGDUO XR 10mg;500mg Tablet USFDA Approved.
	For generic drugs (me-too status)	Dapa-Met XR Tablet 10/500mg Reg No. 112539 M/s Hilton Pharma (Pvt) Limited.
	Name and address of API manufacturer.	**Dapagliflozin;** M/s Fuxin Long Rui Pharmaceutical Co. Ltd. Flouride Industrial Park, Fumeng (Yi Ma tu), Fuxin City, Liaoning Province China. **Metformin HCl;** M/s Aarti Drugs Limited, Plot No. 211-213, Road No. 2, G.I.D.C., Sarigram Dist. Valsad, Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties,

		solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Dapagliflozin;** DG-20190327-D01-DG06-05 (2001R0056) **Metformin HCl;** MEF/10030953 (2008R0046)
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. (48 months for metformin HCl, rest of the conditions are same for both drug sisbtances.) **Dapagliflozin;** 160108, 160124, 160220. **Metformin HCl;** MEF/1410027, MEF/1410028, MEF/1410029.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Deglu-Met XR 10/500 batch ST21C017. **Reference product:** Xigduo XR 10/500mg Tablet, Batch No. LT0188 manufactured by M/s AstraZeneca Pharmaceuticals AB Sweden. **Tests done:** Physical Attributes, Identification, Assay, content uniformity. **CDP:** **pH 1.2:** 90.89, 60.18 **pH 4.5:** 78.40, 76.87 **pH 6.8:** 81.90, 76.27
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Dapagliflozin;** M/s Fuxin Long Rui Pharmaceutical Co. Ltd. Flouride Industrial Park, Fumeng (Yi Ma tu), Fuxin City, Liaoning Province China. **Metformin HCl;** M/s Aarti Drugs Limited, Plot No. 211-213, Road No. 2, G.I.D.C., Sarigram Dist. Valsad, Gujrat India.
API Lot No.	**Dapagliflozin;** DG-20190327-D01-DG06-05 (2001R0056) **Metformin HCl;** MEF/10030953 (2008R0046)
Description of Pack (Container closure system)	Pink to dark pink colour, oblong shaped film coated tablets, in Alu-Alu blister of 7's packed in UC of 14's.

Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST21C017	ST21C018	-
Batch Size	5000 tablets	5000 tablets	-
Manufacturing Date	03.2021	03.2021	-
Date of Initiation	20.04.2021	20.04.2021	-
No. of Batches	2		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin;** M/s Fuxin Long Rui Pharmaceutical Co. Ltd. Copy of License No. Liao20150233 issued by FDA Liaoning China, valid till 20.12.2022 is submitted. **Metformin HCl;** M/s Aarti Drugs Limited. Copy of GMP certificate No. 20031933 valid till 19.03.2023 issued by Food and Drug Control Administration, Gujrat State India is Submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin;** Batch No.: DG-20190327-D01-DG06-05 Mfg date: 05.10.2019 EXP: 04.10.2021 Quantity: 1.5kg Invoice No.: HN1912054-H Invoice date: 05.12.2019 Cleared by: AD I&E DRAP Islamabad. **Metformin HCl;** Batch No.: MEF/10030953 Mfg date: 03.2020 EXP: 02.2025 Quantity: 1000Kg Invoice No.: EXP/302/21-21 Invoice date: 15.05.2020 Cleared by: AD I&E DRAP Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
200.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000417
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 3-16/2018-Addl. Dir. (QA&LT)-1 dated 04.01.2022 valid till 02.01.2024 issued by DRAP Islamabad is submitted.
	Evidence of approval of manufacturing facility	Copy of section approval letter No. 1-1/96-Lic(Vol-II) dated 13.06.2017 is submitted. Tablet Section (general)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23677 dated 22.08.2022
	Details of fee submitted	**PKR 30,000/-** Slip No. 4535473015 dated 22.08.2022
	The proposed proprietary name / brand name	**Deglu-Met XR 10mg/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Dapagliflozin as propendiol monohydrate..10mg Metformin HCl (extended release)……1000mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs ATC Code: A10BD15
	Pharmaceutical form of applied drug	Yellow colour, oblong shaped, dapagliflozin (IR) Metformin (XR) film coated tablet.
	Reference to Finished product specifications	**Innovator Specifications**
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XIGDUO XR 10mg;1gm Tablet USFDA Approved.
	For generic drugs (me-too status)	Dapa-Met XR Tablet 10/1000mg Reg No. 105284 M/s Hilton Pharma (Pvt) Limited.
	Name and address of API manufacturer.	**<u>Dapagliflozin;</u>** M/s Fuxin Long Rui Pharmaceutical Co. Ltd. Flouride Industrial Park, Fumeng (Yi Ma tu), Fuxin City, Liaoning Province China. **<u>Metformin HCl;</u>** M/s Aarti Drugs Limited, Plot No. 211-213, Road No. 2, G.I.D.C., Sarigram Dist. Valsad, Gujrat India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Dapagliflozin;** DG-20190327-D01-DG06-05 (2001R0056) **Metformin HCl;** MEF/10030953 (2008R0046)
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. (48 months for metformin HCl, rest of the conditions are same for both drug sisbtances.) **Dapagliflozin;** 160108, 160124, 160220. **Metformin HCl;** MEF/1410027, MEF/1410028, MEF/1410029.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Deglu-Met XR 10/1000 batch ST21H020. **Reference product:** Xigduo XR 10/1000mg Tablet, Batch No. MA0477 & LT0176 manufactured by M/s AstraZeneca Pharmaceuticals AB Sweden. **Tests done:** Physical Attributes, Identification, Assay, content uniformity. **CDP:** **pH 1.2:** 91.15, 75.85 **pH 4.5:** 93.70, 80.58 **pH 6.8:** 91.53, 88.91
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	**Dapagliflozin;** M/s Fuxin Long Rui Pharmaceutical Co. Ltd. Flouride Industrial Park, Fumeng (Yi Ma tu), Fuxin City, Liaoning Province China. **Metformin HCl;** M/s Aarti Drugs Limited, Plot No. 211-213, Road No. 2, G.I.D.C., Sarigram Dist. Valsad, Gujrat India.		
API Lot No.	**Dapagliflozin;** DG-20190327-D01-DG06-05 (2001R0056) **Metformin HCl;** MEF/10030953 (2008R0046)		
Description of Pack (Container closure system)	Yellow colour, oblong shaped film coated tablets, in Alu-Alu blister of 7's packed in UC of 14's.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST21H020	ST21H021	-
Batch Size	5000 tablets	5000 tablets	-
Manufacturing Date	08.2021	08.2021	-
Date of Initiation	06.08.2021	06.08.2021	-
No. of Batches	2		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin;** M/s Fuxin Long Rui Pharmaceutical Co. Ltd. Copy of License No. Liao20150233 issued by FDA Liaoning China, valid till 20.12.2022 is submitted. **Metformin HCl;** M/s Aarti Drugs Limited. Copy of GMP certificate No. 20031933 valid till 19.03.2023 issued by Food and Drug Control Administration, Gujrat State India is Submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin;** Batch No.: DG-20190327-D01-DG06-05 Mfg date: 05.10.2019 EXP: 04.10.2021 Quantity: 1.5kg Invoice No.: HN1912054-H Invoice date: 05.12.2019 Cleared by: AD I&E DRAP Islamabad. **Metformin HCl;** Batch No.: MEF/10030953 Mfg date: 03.2020 EXP: 02.2025 Quantity: 1000Kg Invoice No.: EXP/302/21-21 Invoice date: 15.05.2020 Cleared by: AD I&E DRAP Islamabad.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted analytical record for product testing.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Approvd.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

201.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hansel Pharmaceuticals (Pvt) Ltd. Plot No.2, Pharma City, 30Km, Multan Road, Lahore-Pakistan. (DML No. 000581)**
	Name, address of Manufacturing site.	M/s Hansel Pharmaceuticals (Pvt) Ltd. Plot No.2, Pharma City, 30Km, Multan Road, Lahore-Pakistan. DML No. 000581
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 285/2019-DRAP (AD-785696-228) dated 10.10.2019 valid till 15.05.2020, issued by DRAP Lahore is submitted.
	Evidence of approval of manufacturing facility	Copy of Section approval letter No. 1-9/2001-Lic dated 17.06.2011 is submitted. Relocated to ground floor vide letter No. 1-9/2001-Lic(Vol-II) dated 03.10.2019. Injectable (Hormones)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23962 dated 24.08.2022
	Details of fee submitted	**PKR 30,000/-** Slip No. 195282574437 dated 24.06.2022
	The proposed proprietary name / brand name	**Kevi 500mg+10mg/2ml IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2 ml ampoule contains; Hydroxyprogesterone Caproate……500mg Estradiol Valerate …….10mg
	Pharmacotherapeutic Group of (API)	hydroxyprogesterone and estrogen ATC Code: G03FA02
	Pharmaceutical form of applied drug	Solution for IM injection in 2ml ampoule.
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be verified.

	For generic drugs (me-too status)	Gravibinan Injection Reg. No. 000798 M/s Bayer Pharmaceuticals
	Name and address of API manufacturer.	**Hydroxyprogesterone Caproate** M/s Taizhou Taifa Pharmaceuticals Co. Ltd. No. 14, Industrial East Road, Xianju, Zhejiang, 317300 China. **Estradiol Valerate** M/s AGS Biochem Pvt. Ltd. Ganganagar 24PGS, W.B India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Hydroxyprogesterone 5260-201201
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. Hydroxyprogesterone: 17-200305001, 17-200305002, 17-200305003.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Kevi Batch No. 571. **Reference product:** Gravibinan, Batch No. ___, manufactured by M/s Bayer. **Tests done:** Description, Identification, particulate matter, assay, sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API	**Hydroxyprogesterone Caproate**	

	M/s Taizhou Taifa Pharmaceuticals Co. Ltd. No. 14, Industrial East Road, Xianju, Zhejiang, 317300 China. **Estradiol Valerate** M/s AGS Biochem Pvt. Ltd. Ganganagar 24PGS, W.B India.		
API Lot No.	**Estradiol Valerate** Batch No.: ESVZ01A016 **Hydroxyprogesterone Caproate** Batch No.: 5260-201201		
Description of Pack (Container closure system)	2ml amber colour glass ampoule.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	H-571	H-572	H-573
Batch Size	2000 ampoules	2000 ampoules	2000 ampoules
Manufacturing Date	01.2021	01.2021	01.2021
Date of Initiation	27.01.2021	28.01.2021	29.01.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Hydroxyprogesterone Caproate** Copy of DML No. Zhe20190003 dated 26.03.2019 issued by FDA Zhejiang China is submitted. Valid till 25.03.2024 **Estradiol Valerate** Copy of certificate No. DCWB/Sch M/Certificate/2020/1910 dated 09.01.2020 valid till 24.01.2021, issued by Directorate of drug control West Bengal India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Hydroxyprogesterone Caproate** Batch No.: 5260-201201 Mfg date: 07.12.2020 Retest: 06.12.023 Quantity: 25kg Invoice No.: 21SK02013 Invoice date: 21.12.2020 Cleared by: AD I&E DRAP Lahore. **Estradiol Valerate** Batch No.: ESVZ01A016 Mfg date: 05.2019 Retest: 04.2023 Quantity: 20gm Invoice No.: EXP-ESVZ-05-2019 Invoice date: 19.07.2019 Cleared by: AD I&E DRAP Lahore.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted analytical record for product testing.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	The label applied is 250mg+5mg/ml solution, the label is required to be in accordance with 2ml ampoule. Clarify
2.	-	Valid RRA reference of applied product having exact same strength in 2ml ampoule is required.
3.	3.2.S	The S-Part of Estradiol is not submitted.
4.	3.2.P.2	In pharmaceutical equivalence, it is not clarified what was the strength, batch No. mfg date and exp date of the reference product (Gravibinan) (The strength of reference product must 500mg+10mg/2ml, the product cannot be compared with product having strength of 250mg+5mg/1ml)

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

202.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s News Pharma, Plot No. 42, Sunder Industrial Estate Lahore (DML No. 000775)**
	Name, address of Manufacturing site.	M/s News Pharma, Plot No. 42, Sunder Industrial Estate Lahore. DML No. 000775
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of inspection report dated 28.07.2021
	Evidence of approval of manufacturing facility	Copy of section approval letter No. 1-14/2006-Lic dated 18.02.2013 is submitted. Liquid Injection (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24961 dated 02.09.2022
	Details of fee submitted	PKR 30000/- Slip No. 10508216678 dated 29.08.2022
	The proposed proprietary name / brand name	**Water for Injection 10ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains; Sterile water for injection…….10ml
	Pharmacotherapeutic Group of (API)	Other antiallergics ATC Code: S01GX09
	Pharmaceutical form of applied drug	Water for injection
	Reference to Finished product specifications	**BP Specifications.**
	Proposed Pack size	10ml

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Water for Injection 10 mL Reg. No. 024684 M/s Pharmatec Pakistan Karachi.
	Name and address of API manufacturer.	**NA**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	NA
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	NA
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** WFI. **Reference product:** WFI, Batch No. __ manufactured by M/s Healthtek Karachi. **Tests done:** physical characteristics, pH, Acidity or Alklimity, conductivity, oxidizable substances, Chlorides, Nitrates, Sulfates, ammonium, Calcium and magnesium, residue on evaporation.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	NA		
API Lot No.	NA		
Description of Pack (Container closure system)	5ml Sterile solution in LDPE bottle, packed in a printed carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03

Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	07.2021	07.2021	07.2021
Date of Initiation	19.07.2021	20.07.2021	21.07.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	NA
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**NA**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	1.3.5	Copy of latest GMP certificate is required.	The firm has submitted copy of inspection report dated 28.07.2021.
2.	3.2.P.8	The stability studies data of 2nd and 3rd time point are required.	The firm has submitted data vide letter No. nil dated 13.02.2024

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

203.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s News Pharma, Plot No. 42, Sunder Industrial Estate Lahore (DML No. 000775)**
	Name, address of Manufacturing site.	M/s News Pharma, Plot No. 42, Sunder Industrial Estate Lahore. DML No. 000775
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of inspection report dated 28.07.2021.
	Evidence of approval of manufacturing facility	Copy of section approval letter No. 1-14/2006-Lic(Vol-I) dated 12.11.2021 is submitted. Oral Liquid General Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25516 dated 08.09.2022
	Details of fee submitted	PKR 30000/- Slip No. 62356233 dated 05.09.2022
	The proposed proprietary name / brand name	**NEW-FYLINE Syrup 100mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains; Doxofylline……100mg
	Pharmacotherapeutic Group of (API)	Xanthines ATC Code: R03DA11
	Pharmaceutical form of applied drug	Syrup.
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	60ml, 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	The firm has submitted reference of product ANSIMAR syrup 2g/100ml AIFA Italy approved.
	For generic drugs (me-too status)	Fylod 100mg/5ml Syrup Reg. No. 092698 M/s Sami Pharmaceuticals Karachi.
	Name and address of API manufacturer.	M/s Bajaj Healthcare Limited Unit-1, N-128/216/217 MIDC, Tarapur, Boisar, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. DOX-0170222
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No. DOXF-0012146, DOXF-0012147, DOXF-0012145
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and

		process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** New-Fyline Syrup **Reference product:** Fylod Syrup, Batch No. __ Exp. manufactured by M/s Sami Karachi. **Tests done:** physical characteristics, pH, identification, uniformity of dosage unit, Deliverable volume, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Bajaj Healthcare Limited Unit-1, N-128/216/217 MIDC, Tarapur, Boisar, India.		
API Lot No.	DOX-0170222		
Description of Pack (Container closure system)	White colour suspension filled in amber coloured bottles.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	45 bottles	45 bottles	45 bottles
Manufacturing Date	09.2021	09.2021	09.2021
Date of Initiation	28.09.2021	28.09.2021	28.09.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of license No. 25-KV/174 dated 03.01.2022 valid till 31.12.2026, issued by FDA Maharashtra is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Doxofylline** Batch No: DOX-0170222 Mfg: 02.2021 Exp: 01.2025 Quantity: 1kg Invoice No. ES/TP/0058/21-21 Invoice date: 10.09.2021 Clearance done through DHL.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	-	Verifiable evidence of RRA approval is required.	Firm vide letter No. nil dated 13.02.2024 has submitted reference of AIFA Italy approved product.
2.	1.3.5	Copy of latest GMP certificate is required.	The firm has submitted copy of inspection report dated 28.07.2021.
3.	3.2.P.2	The batch Number, mfg date and exp date of reference product (Fylod Syrup) is required.	Firm has submitted following details; Fylod Syrup; Batch No. CQF 06, Mfg date. 06.2021, exp date: 05.2023
4.	3.2.P.1	In formulation, Glycerol and PEG are used, there is no data given for testing of these two excipients for ethylene glycol and diethylene glycol levels. Justify.	Firm has submitted test report issued by PCSIR Lahore for testing of Glycerine batch No. 000263IMD3C5L & propylene glycol batch No. IP03-202308233. Wherein it is mentioned that Ethylene glycol and Diethylene glycol is not detected.
5.	3.2.P.8	In stability data summary sheets, the description is mentioned as *"White colour suspension filled in amber coloured bottles."* Whereas application submitted is of oral syrup. Clarification is required for this discrepancy. Further its also not mentioned that bottle will be of either glass or PET.	The firm has submitted that product is a syrup and it's not a suspension. Container closure system is Amber coloured PET Bottle.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

204.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s News Pharma, Plot No. 42, Sunder Industrial Estate Lahore (DML No. 000775)**
	Name, address of Manufacturing site.	M/s News Pharma, Plot No. 42, Sunder Industrial Estate Lahore. DML No. 000775
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of inspection report dated 28.07.2021.
	Evidence of approval of manufacturing facility	Copy of section approval letter No. 1-14/2006-Lic(Vol-I) dated 12.11.2021 is submitted. Oral Liquid General Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24960 dated 02.09.2022
	Details of fee submitted	PKR 30000/- Slip No. 61114188668 dated 29.08.2022
	The proposed proprietary name / brand name	**NEW-ZONE 2g IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Ceftriaxone sodium eq Ceftriaxone…… 2g
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins ATC Code: J01DD04
	Pharmaceutical form of applied drug	Powder for solution for IV infusion.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CEFTRIAXONE 2G POWDER FOR SOLUTION FOR INJECTION/INFUSION MHRA Approved.
	For generic drugs (me-too status)	Andel 2g IV Reg. No. 110976 M/s Invictus Pharmaceuticals Rawalpindi.
	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd. Economic & technological Development Zone, First Medical Zone Datong Shanxi China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. Q012105081
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No. 011302001, 011302002, 011302003.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical

		development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** New-Zone 2g Inj **Reference product:** Oxidil 2g Inj, Batch No. __ Exp. manufactured by M/s Sami Karachi. **Tests done:** physical characteristics, Uniformity of dosage unit, Water determination, pH, Assay. Deliverable volume, BET, Particulate matter.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd. Economic & technological Development Zone, First Medical Zone Datong Shanxi China.		
API Lot No.	Q012105081		
Description of Pack (Container closure system)	White to yellowish crystalline powder filled in transparent glass vial.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	07.2021	07.2021	07.2021
Date of Initiation	28.07.2021	28.07.2021	28.07.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. SX20180229 dated 06.06.2018 valid till 05.06.2023 issued by FDA Shanxi province China is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ceftriaxone Sodium** Batch No: Q012105081 Mfg: 28.05.2021 Exp: 27.05.2024 Quantity: 1kg Invoice No. W210622 Invoice date: 23.06.2021 Clearance done by: AD I&E DRAP Lahore.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted analytical record for product testing.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	1.3.5	Copy of latest GMP certificate is required.	The firm has submitted copy of inspection report dated 28.07.2021.
2.	3.2.P.2	The batch Number, mfg date and exp date of reference product (Oxidil 2g) is required.	The firm has submitted following details; Oxidil 2g Injection, Batch No. MCE 011, Mfg date. 05.2021, Exp date 04.2023
3.	-	Copy of AD attested invoice or clearance certificate of drug substance is required.	The firm has submitted copy of AD I&E Lahore attested Invoice for clearance of drug substance.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

205.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories (Pvt.) Ltd., 16-KM, Multan Road, Lahore. (DML No. 000228)**
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories (Pvt.) Ltd., 16-KM, Multan Road, Lahore. DML No. 000228
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 93/2020-DRAP (AD-2003099-790) dated 09.06.2020 valid till 03.02.2022 issued by DRAP Lahore is submitted.
	Evidence of approval of manufacturing facility	Copy of letter of layout regularization is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24964 dated 02.09.2022
	Details of fee submitted	**PKR 30,000/-** Slip No. 836342734437 dated 02.08.2022
	The proposed proprietary name / brand name	**RIVOXAN 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Rivaroxaban……..…20mg

	Pharmacotherapeutic Group of (API)	Direct factor Xa inhibitors ATC Code: B01AF01
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rivaroxaban 20 mg film-coated tablets MHRA Approved.
	For generic drugs (me-too status)	Xarelto 20Mg Tablets. Reg. No. 072550 M/s Novartis Pharma (Pakistan) Limited
	Name and address of API manufacturer.	M/s Zhejiang Supor Pharmaceutical Co. Ltd., Yuedong Road, Paojiang Industrial Zone, Shaoxing, Zhejiang China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 032-20040611
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. 032-141202, 032-141203, 032-141204
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Rivaroxaban 20mg Tablet Batch No. RIVA-20/T002. **Reference product:** XARELTO 20mg Tablets, Batch No. BXJANN1, mfg: 04.2019, Exp.: 04.2022 manufactured by M/s Bayer AG Germany.

		Tests done: Assay, DT, Dissolution **CDP;** **pH 1.2:** More than 85% in 15 min **pH 4.5:** More than 85% in 15 min **pH 6.8:** More than 85% in 15 min
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang Supor Pharmaceutical Co. Ltd., Yuedong Road, Paojiang Industrial Zone, Shaoxing, Zhejiang China.		
API Lot No.	032-200406U		
Description of Pack (Container closure system)	Alu-Alu Blister.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RIVA-20/T001	RIVA-20/T002	RIVA-20/T003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	05.2021	12.2021	12.2021
Date of Initiation	16.06.2021	24.01.2022	24.01.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML vide No. Zhe 20040279 valid till 30.05.21024 issued by Zhejiang FDA is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Rivaroxaban** Batch No.: 032-200406U Mfg date: 16.04.2020 Retest: 15.04.2025 Quantity: 0.365kg Invoice No.: XZD21-041 Invoice date: 26.03.2021 Cleared by: AD I&E DRAP Lahore
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator:		

Sr. No.	Section	Observation	Reply
1.	3.2.P.8	For trial batches RIVA-20/T002 & RIVA-20/T003, stability studies data of 3rd time point is required.	Submitted vide letter No. PHL/0124/REG/057 dated 09.01.2024.

Decision: Approved.

The registration letter will be issued after the submission of GMP ststus verification

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

206.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories (Pvt.) Ltd., 16-KM, Multan Road, Lahore. (DML No. 000228)**
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories (Pvt.) Ltd., 16-KM, Multan Road, Lahore. DML No. 000228
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 93/2020-DRAP (AD-2003099-790) dated 09.06.2020 valid till 03.02.2022 issued by DRAP Lahore is submitted.
	Evidence of approval of manufacturing facility	Copy of letter of layout regularization is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 29963 dated 02.09.2022
	Details of fee submitted	**PKR 30,000/-** Slip No. 3079669934 dated 02.08.2022
	The proposed proprietary name / brand name	**RIVOXAN 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Rivaroxaban……..…15mg
	Pharmacotherapeutic Group of (API)	Direct factor Xa inhibitors ATC Code: B01AF01
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	10’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	RIVAROXABAN SANDOZ 15 MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Xarelto 15mg Tablets. Reg. No. 072549 M/s Bayer Pakistan

	Name and address of API manufacturer.	M/s Zhejiang Supor Pharmaceutical Co. Ltd., Yuedong Road, Paojiang Industrial Zone, Shaoxing, Zhejiang China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 032-20040611
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. 032-141202, 032-141203, 032-141204
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Rivaroxaban 15mg Tablet Batch No. TR001 **Reference product:** XARELTO 15mg Tablets, Batch No. BXJLBB1, mfg: 02.2021, Exp.: 02.2023 manufactured by M/s Bayer AG Germany. **Tests done:** Assay, DT, Dissolution **CDP;** **pH 1.2:** More than 85% in 15 min **pH 4.5:** More than 85% in 15 min **pH 6.8:** More than 85% in 15 min
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Zhejiang Supor Pharmaceutical Co. Ltd., Yuedong Road, Paojiang Industrial Zone, Shaoxing, Zhejiang China.
API Lot No.	032-200406U

Description of Pack (Container closure system)	Alu-Alu Blister.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RIVA-15/T001	RIVA-15/T002	RIVA-15/T003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	05.2021	12.2021	12.2021
Date of Initiation	16.06.2021	08.01.2022	08.01.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML vide No. Zhe 20040279 valid till 30.05.21024 issued by Zhejiang FDA is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Rivaroxaban** Batch No.: 032-200406U Mfg date: 16.04.2020 Retest: 15.04.2025 Quantity: 0.365kg Invoice No.: XZD21-041 Invoice date: 26.03.2021 Cleared by: AD I&E DRAP Lahore
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	3.2.P.8	For trial batches RIVA-15/T002 & RIVA-15/T003, stability studies data of 3rd time point is required.	Submitted vide letter No. PHL/0124/REG/057 dated 09.01.2024.

Decision: Approved. The registration letter will be issued after the submission of GMP ststus verification

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

207.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories (Pvt.) Ltd., 16-KM, Multan Road, Lahore. (DML No. 000228)**

	Name, address of Manufacturing site.	M/s Pharmedic Laboratories (Pvt.) Ltd., 16-KM, Multan Road, Lahore. DML No. 000228
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 93/2020-DRAP (AD-2003099-790) dated 09.06.2020 valid till 03.02.2022 issued by DRAP Lahore is submitted.
	Evidence of approval of manufacturing facility	Copy of letter of layout regularization is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24962 dated 02.09.2022
	Details of fee submitted	**PKR 30,000/-** Slip No. 71568346 dated 02.08.2022
	The proposed proprietary name / brand name	**RIVOXAN 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Rivaroxaban……..…10mg
	Pharmacotherapeutic Group of (API)	Direct factor Xa inhibitors ATC Code: B01AF01
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	10’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	RIVAROXABAN MILPHARM 10 MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Xarelto 10mg Tablets. Reg. No. 059057 M/s Bayer Pakistan
	Name and address of API manufacturer.	M/s Zhejiang Supor Pharmaceutical Co. Ltd., Yuedong Road, Paojiang Industrial Zone, Shaoxing, Zhejiang China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications,

		analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 032-20040611
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. 032-141202, 032-141203, 032-141204
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Rivaroxaban 10mg Tablet Batch No. TR002 **Reference product:** XARELTO 10mg Tablets, Batch No. BXJJL41, mfg: 10.2020, Exp.: 10.2023 manufactured by M/s Bayer AG Germany. **Tests done:** Assay, DT, Dissolution **CDP;** **pH 1.2:** More than 85% in 15 min **pH 4.5:** More than 85% in 15 min **pH 6.8:** More than 85% in 15 min
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Supor Pharmaceutical Co. Ltd., Yuedong Road, Paojiang Industrial Zone, Shaoxing, Zhejiang China.		
API Lot No.	032-200406U		
Description of Pack (Container closure system)	Alu-Alu Blister.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RIVA-10/T001	RIVA-10/T002	RIVA-10/T003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	05.2021	12.2021	12.2021
Date of Initiation	16.06.2021	24.01.2022	24.01.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML vide No. Zhe 20040279 valid till 30.05.21024 issued by Zhejiang FDA is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Rivaroxaban** Batch No.: 032-200406U Mfg date: 16.04.2020 Retest: 15.04.2025 Quantity: 0.365kg Invoice No.: XZD21-041 Invoice date: 26.03.2021 Cleared by: AD I&E DRAP Lahore
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	3.2.P.8	For trial batches RIVA-10/T002 & RIVA-10/T003, stability studies data of 3rd time point is required.	Submitted vide letter No. PHL/0124/REG/057 dated 09.01.2024.

Decision: Approved. The registration letter will be issued after the submission of GMP ststus verification

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

208.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s The Searle Company Limited, F-319, SITE, Karachi (DML No. 000016)**
	Name, address of Manufacturing site.	M/s Searle Pakistan Limited, C-14, Manghopir Road, SITE Karachi. DML No. 000012
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Not submitted
	Evidence of approval of manufacturing facility	Copy of section approval letter No. 2-1/2004-Lic (Vol-II) dated 26.10.2020 is submitted. Sachet (Hormone)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22141 dated 04.08.2022
	Details of fee submitted	**PKR 75,000/- (Contract application)** Slip No. 565035523053 dated 27.06.2022
	The proposed proprietary name / brand name	**Andrex Gel 1%**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5g of Gel contains; Testosterone……50mg
	Pharmacotherapeutic Group of (API)	Androgen ATC Code: G03EA02
	Pharmaceutical form of applied drug	Transdermal Gel
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	10's 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TESTOGEL 50 MG TRANSDERMAL GEL IN SACHET MHRA Approved.
	For generic drugs (me-too status)	Testiva Gel Reg No. 097085 M/s Searle Pakistan Limited.
	Name and address of API manufacturer.	M/s Ipca Laboratories Limited Plot No. 23-24, G.I.D.C Estate, Nandesari, Vadodara, Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 18006TS1RN
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. 4016TS1RN, 4017TS1RN, 4018TS1RN,
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and

		process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Andrex Gel 50mg/5g Batch No. C0024. **Reference product:** Androgel 50mg/g, Batch No. 33147 mfg 01.2022 exp 01.2025, manufactured by M/s Laboratories Bezen International CAC. **Tests done:** Appearance, identification, assay, viscosity, pH and weight variation.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Ipca Laboratories Limited Plot No. 23-24, G.I.D.C Estate, Nandesari, Vadodara, Gujrat India		
API Lot No.	18006TS1RN		
Description of Pack (Container closure system)	Alu-Alu Sachet		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C0001	C002	C003
Batch Size	12000 sachet	12000 sachet	12000 sachet
Manufacturing Date	01.2021	01.2021	01.2021
Date of Initiation	02.02.2021	02.02.2021	02.02.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 19051345 dated 21.05.2019 valid till 20.05.2022 issued by Food and Drugs Control Administration Gujrat India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Testosterone USP** Batch No.: 18006TS1RN Mfg date: 04.2018 Exp dt: 03.2021 Quantity: 30kg Invoice No.: MEG1819/1631439 Invoice date: 22.08.2018 Cleared by: AD I&E DRAP Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	-	Applicant firm does not have Hormone section. The product is a hormonal product. The manufacturer does have sachet (Hormone) Section.	The firm has submitted copy of renewal of DML letter No. 2-1/2004-Lic (Vol-II) dated 20.10.2020 wherein sachet hormone section is approved.
2.	1.3.5	Copy of valid GMP certificate of drug product manufacturer is required.	Response submitted vide letter No. RA/SR/01/2K24/LOC(TSCL)-275 dated 04.01.2024. Copy of GMP certificate No. 10/2022-DRAP(K) dated 15.02.2022 valid till 07.10.2023 is submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

209.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s The Searle Company Limited, F-319, SITE, Karachi (DML No. 000016)**
	Name, address of Manufacturing site.	M/s The Searle Company Limited, F-319, SITE, Karachi. DML No. 000016
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not submitted
	Evidence of approval of manufacturing facility	Copy of section approval letter No. 2-6/2018-Lic (Vol-IV) dated 29.10.2020 is submitted. Tablet (General) Section
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22533 dated 10.08.2022
	Details of fee submitted	**PKR 75,000/-** Slip No. 9093861885 dated 21.07.2022
	The proposed proprietary name / brand name	**NEXLETOL Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Bempedoic acid……180mg
	Pharmacotherapeutic Group of (API)	Other lipid modifying agents ATC Code: C10AX15

	Pharmaceutical form of applied drug	Peach coloured, oblong shaped biconvex film coated tablet. Break line on one side and plain on other side.
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NILEMDO 180MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	**NA**
	Name and address of API manufacturer.	M/s Metrochem API Private Limited, Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. PD/BMP-P/20010
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 18 months. Batch No. BMPD-V/A070/44, BMPD-V/A070/45, BMPD-V/A070/46
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Bempedoic acid 180mg Tablet, Batch No. 21PD-088 **Reference product:** Nilemdo 180mg tablet, Batch No. 356259 exp 02.2024, manufactured by M/s Laboratories Bezen International CAC.

		Tests done: Physical appearance, assay, dissolution, content univormity, related substances. **CDP:** **F2 at pH 1.2=** 12.75 **F2 at pH 4.5 =** 11.11 **F2 at pH 6.8 =** 59.45
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Metrochem API Private Limited, Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, India.		
API Lot No.	18006TS1RN		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21PD-088	21PD-097	21PD-098
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	04.2021	05.2021	05.2021
Date of Initiation	06.2021	06.2021	06.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. E-2242912/DD/DCA/VSP/2023 dated 01.12.2023 issued by Drug Control Administration Andhra Pradesh valid till 30.11.2024 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Bampedoic Acid** Batch No.: PD/BMP-P/20010 Mfg date: 12.2020 Exp dt: 11.2022 Quantity: 4.8kg Invoice No.: DE/20/0176 Invoice date: 23.02.2021 Cleared by: AD I&E DRAP Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	3.2.S.7 & 3.2.P.8	The stability data of drug substance submitted is only upto for 18 months and proposed shelf life of drug product is 24 months. Justify and also submitted complete stability data of drug substance.	Response submitted vide letter No. nil dated nil. Firm has submitted stability data of following batches of drug substance upto 36 months (3 years) as per requirements of Zone II; BMPD-V/A070/44, BMPD-V/A070/45, BMPD-V/A070/46.
2.	3.2.P.2	In comparative dissolution it is concluded that CDP of test and reference product show equivalence, whereas F2 factor for CDP at pH 1.2 is 12.75 and at pH 4.5 is 11.11. The F2 factor is below acceptance criteria. Justify.	The firm has stated that it was a typographic error and by mistake they had written F1 values in F2 column and vice versa. Correct F2 values at different pH are given below; **F2 at pH 1.2=** 59.93 **F2 at pH 4.5 =** 52.36 **F2 at pH 6.8 =** 59.45

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

210.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s ATCO Laboratories limited, B-18, S.I.T.E., Karachi (DML No. 000188)**
	Name, address of Manufacturing site.	M/s ATCO Laboratories limited, B-18, S.I.T.E., Karachi. DML No. 000188
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 160/2020-DRAP (K) dated 24.12.2020 valid till 23.12.2022 issued by DRAP Karachi is submitted.
	Evidence of approval of manufacturing facility	Copy of section approval letter No. 2-5/85-Lic (Vol-II) dated 04.07.2022 is submitted. Eye/Ear/Nasal Drops and nebulizers/inhalation solution- General Section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25513 dated 08.09.2022
	Details of fee submitted	**PKR 75,000/-** Slip No. 92711324565 dated 19.12.2022
	The proposed proprietary name / brand name	**WINOLAP FORTE Ophthalmic Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains;

		Olopatadine hydrochloride eq to Olopatadine……..…7mg (0.7% w/v)
	Pharmacotherapeutic Group of (API)	Other antiallergics ATC Code: S01GX09
	Pharmaceutical form of applied drug	Ophthalmic solution.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	2.5ml, 5ml, 7.5ml, 10ml and 15ml.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PATADAY Once Daily Relief, Olopatadine hydrochloride eq 0.7% base USFDA Approved.
	For generic drugs (me-too status)	**NA. Fee is submitted for New Drug Product.**
	Name and address of API manufacturer.	M/s Binha Gaolou Chemical Co. Ltd. 2nd Zhongshan Road, Chemical park, Binhai Economic Development Zone, Binhai County, Yancheng Jiangsu China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 200902
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. 170901, 171101, 170801, 170901, 171101.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Winlap Forte Ophthalmic Sol Batch No. AU331C 5ml LDPE. **Reference product:** Pataday Ophthalmic Sol 0.7%, Batch No. 10YTF 2.5ml LDPE, manufactured by M/s Alcon Laboratories Inc. Pictorial evidence is submitted. **Tests done:** physical characteristics, Identification, Assay, pH, Content of preservative, Osmolality, Impurities
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Binha Gaolou Chemical Co. Ltd. 2nd Zhongshan Road, Chemical park, Binhai Economic Development Zone, Binhai County, Yancheng Jiangsu China.		
API Lot No.	20092		
Description of Pack (Container closure system)	5ml Sterile solution in LDPE bottle, packed in a printed carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	AU333C	AU331C	AU332C
Batch Size	151 bottles (1500ml)	150 bottles (1500ml)	150 bottles (1500ml)
Manufacturing Date	09.2021	09.2021	09.2021
Date of Initiation	08.10.2021	08.10.2021	08.10.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML No. Beij20172001 dated 25.01.2022 valid till 24.01.2027, issued by CFDA China is submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Olopatadine HCl USP** Batch No.: Mfg date: 05.2021 Quantity: 0.25kg Invoice No.: 20144ALL Invoice date: 20.10.2020 Cleared by: AD I&E DRAP Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Agenda of Evaluator PEC-XI

Case No. 01; Routine registration applications of Human Drugs on Form 5F

211.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals Pvt. Ltd., Plot No# 129, Sunder Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals Pvt. Ltd., Plot No# 129, Sunder Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 08-09-2021 based on inspection conducted on 08-09-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-51/2004-Lic dated 07-02-2014 which specifies Tablet (General Human) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 22955 dated 15-08-2022
	Details of fee submitted	Rs.30,000/- dated 06-07-2022 (Deposit slip#84133059102)
	The proposed proprietary name / brand name	**Pregabalin 330mg ER Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Pregabalin……330mg
	Pharmaceutical form of applied drug	Extended Release Oral solid tablet
	Pharmacotherapeutic Group of (API)	Anticonvulsant
	Reference to Finished product specifications	In-house specifications
	Proposed Pack size	3x10's, 1x10's, 2x10's, 2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA CR extended-release tablets (82.5mg, 165mg, 330 mg) USFDA Approved.
	For generic drugs (me-too status)	NA

	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd., Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against Lyrica CR 330mg Tablet by performing quality tests (Description, Identification, Assay, Dissolution). CDP has been performed against a comparator product ***(name not mentioned)*** in Acid media pH 1.2, acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm have submitted method validation studies including linearity, range, accuracy, precision, specificity and robustness.

STABILITY STUDY DATA	
Manufacturer of API	M/s CTX Lifesciences Pvt. Ltd., Block No. 251-252 Sachin-Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
API Lot No.	21PL000050
Description of Pack	Alu-Alu blister packed in unit carton

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TPU001	TPU002	TPU003
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	21-12-2021	23-12-2021	25-12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of M/s CTX Lifesciences Pvt. Ltd., Block No. 251/P, 252/P, 253 TO 255, 256/P, 258/P, 276/P, 277, 278/P, 279 TO 282, 283/P, 284/P, GIDC, City: Sachin, District; Surat – Gujarat state, INDIA issued by Food & Drugs Control Administration Gujarat State India valid upto 01-07-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. EI/3012100599 dated 19-11-2021 for import of 50kg of Pregabalin (Batch# 21PL000050) in name of M/s Wimits Pharmaceuticals (Pvt.) Ltd., attested by AD (I&E) DRAP Lahore dated 29-11-2021
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.1	• Submit differential fee Rs. 45000/- as the applied product is a new drug molecule / New formulation	• Firm has submitted differential Fee Rs. 45000/- on deposit slip No. 5205891368 as applied product is a new drug molecule. However, upon online verification the invoice amount is Rs. 30,000/- while paid amount is Rs. 45,000/-
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Firm has submitted a copy of valid DML
1.4	• Clarification is required as you have applied for generic drug product while	• The firm submitted that it was mistakenly done please considered as New Drug Molecule and submitted revised document

	the applied product is a new drug molecule / New formulation	
1.5.2	• Clarification is required as you have applied for extended release tablets while the reference formulation is film coated extended release tablets or revise your label claim as per reference formulation along with submission of applicable fee.	• Firm has revised the label claim as per reference formulation without submission of fee. The revise label claim is as under: Each Film Coated Extended Release tablet contains: Pregabalin.....330mg
1.6.5	• Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	• Firm has submitted copy of cGMP certificate of M/s CTX Lifesciences Pvt. Ltd., Block No. 251/P, 252/P, 253 TO 255, 256/P, 258/P, 276/P, 277, 278/P, 279 TO 282, 283/P, 284/P, GIDC, City: Sachin, District; Surat – Gujarat state, INDIA issued by Food & Drugs Control Administration Gandhinagar India valid upto 29-05-2025.
3.2.S.4	• Justification is required for not performing test for enantiomeric purity (pregabalin related compound A) in batch analysis of drug substance by drug product manufacturer as recommended by USP	• The firm submitted that we relied upon the drug substance manufacturer for the enantiomeric purity test. The performed and result of analysis as per COA is submitted.
3.2.S.7	• Submitted drug substance stability summery sheets conclude as: No significant change observed during long term stability upto 60 months when stored at 25˚C ± 2˚C / 60% ± 5%RH, clarification shall be submitted for above	• Firm has again submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per zone IV-A. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
3.2.P.2	• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product. • Details of comparator product including brand name, manufacturer, batch number, manufacturing date, expiry date against which CDP studies is performed • Details of comparator product including manufacturer, batch number, manufacturing date, expiry date against which pharmaceutical equivalence studies is performed	• Firm has submitted compatibility studies of the drug substance with excipients. • The firm has submitted details of comparator / innovator product **Name:** Lyrica CR 330mg Extended Release tablets **Manufacturer:** Pfizer INC, NY, NY 10017 NDC 0071-1029-01 GTIN00300711029018 **B#:** AW6452 • The details of marketing authorization holder and expiry date is not submitted
3.2.P.8	• Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not submitted	• Audit trial reports on product testing is submitted

Decision: Approved with following label claim:
"Each Film Coated Extended Release tablet contains:
Pregabalin ..... 330mg"

Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
212.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals Pvt. Ltd., Plot No# 129, Sunder Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals Pvt. Ltd., Plot No# 129, Sunder Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 08-09-2021 based on inspection conducted on 08-09-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-51/2004-Lic dated 07-02-2014 which specifies Tablet (General Human) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy. No 27735 dated 30-09-2022
	Details of fee submitted	Rs.30,000/- dated 23-09-2022 (Deposit slip#694135047)
	The proposed proprietary name / brand name	**Vozan 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan as Fumarate……10mg
	Pharmaceutical form of applied drug	Oral solid Tablet
	Pharmacotherapeutic Group of (API)	Potassium Competitive acid blocker (P-CAB)
	Reference to Finished product specifications	In house specifications
	Proposed Pack size	1x10's, 2x10's, 2x7's, 3x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab 10mg tablet by M/s Takeda Pharmaceutical Company Limited, PMDA Japan Approved.
	For generic drugs (me-too status)	Vocinti Tablet 10mg by M/s The Searle Company Limited, (Reg. No. 108835)
	Name and address of API manufacturer.	M/s Enantiotech Corporation Limited., No.6 Zhongjing RD, Zhongshan Torch Hi-Tech Industrial Development Zone, Guangdong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification,

		batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the comparator product Vonnp 10mg Tablet, by performing quality tests (Identification, Assay, Dissolution). CDP has been performed against the comparator product vonoprazan 10mg Tablet in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including linearity and range, accuracy, precision (Repeatability, Intermediate), specificity, robustness and system suitability.

STABILITY STUDY DATA	
Manufacturer of API	M/s Enantiotech Corporation Limited., No.6 Zhongjing RD, Zhongshan Torch Hi-Tech Industrial Development Zone, Guangdong Province, China
API Lot No.	TAK09-220101
Description of Pack (Container closure system)	Alu-Alu Blister packed in unit carton.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	TVF001	TVF002	TVF003
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	18-06-2022	20-06-2022	22-06-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Enantiotech Corporation Limited., Zhongshan Torch Hi-Tech Industrial Development Zone, Guangdong Province, China issued by Zhongshan Medical Association China valid upto 30-12-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 dated 27-05-2022 for import of 500g Vonoprazan fumarate in name of M/s Wimits Pharmaceuticals Pvt. Ltd., Lahore attested by AD (I&E) DRAP Lahore dated 27-05-2022.
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Firm has submitted a copy of valid DML
1.6.5	• Valid cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• The firm has again submitted copy of cGMP certificate of M/s Enantiotech Corporation Limited., No.6 Zhongjing Road, Zhongshan Torch Hi-Tech Industrial Development Zone, Zhongshan City, Guangdong Province, China issued by Guangdong Pharmaceutical Industry Association China valid upto 09-06-2025

<table>
<tr><td>3.2.S.4</td><td>• Justification shall be submitted for using different chromatographic conditions (wavelength, injection volume, mobile phase) for assay test by drug product manufacturer than that by substance manufacturer
• Justification shall be submitted for not performing the test for fumaric acid content in batch analysis of drug substance by drug product manufacturer as recommended by drug substance manufacturer</td><td>• Firm has revised chromatographic method as per drug substance manufacturer
• Fumaric acid content is performed and revised COA of drug product manufacturer is submitted</td></tr>
<tr><td>3.2.P.2</td><td>• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.
<table>
<tr><th>Applied product</th><th>TAKECAB Tablets 10mg</th></tr>
<tr><td>Vonoprazan Fumarate</td><td>Vonoprazan Fumarate</td></tr>
<tr><td>Lactose monohydrate, Mannitol, Avicel Ph 101, Klucel, Cross carmellose sodium, sodium starch glycolate, magnesium stearate, Tabcoat white, isopropyl alcohol, purified water</td><td>D-mannitol, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, fumaric acid, magnesium stearate, hypromellose, macrogol 6000, titanium oxide, yellow ferric oxide</td></tr>
</table>
• Details of reference product including manufacturer, batch number, manufacturing and expiry date used in pharmaceutical equivalence studies shall be submitted
• Details of comparator product including brand name, manufacturer, batch number, manufacturing and expiry date used in CDP studies shall be submitted
• Justification shall be submitted for not performing the tests in pharmaceutical equivalence studies including the tests recommended by innovator product review document (uniformity of dosage units)
• Justification shall be submitted for not performing pharmaceutical equivalence and CDP studies against the innovator product</td><td>• Firm has submitted compatibility studies of the drug substance with excipients.
• The firm has submitted details of reference product
Name: Voniza 10mg tablets
Manufacturer: M/s Hilton Pharma
B No#: 141102
Mfg date: 11-2021
Exp date; 11-2023
• However, the brand name mentioned in pharmaceutical equivalence studies was vonnp 10mg tablet
• Firm has submitted revised pharmaceutical equivalence report in which test for uniformity of dosage units has been performed.
• The firm submitted that the innovator product is Takeda that is not easily available that is why we use the local product which is easily available in the market</td></tr>
<tr><td>3.2.P.5</td><td>• Justify the variation of dissolution parameters i.e. dissolution medium and time from that recommended by USFDA for the vonoprazan tablets. (use of phosphate buffer pH 6.8 instead of 0.05M acetate buffer pH 4.5, and Q at 30 minutes instead on Q at 15 minutes)</td><td>• The firm submitted that we have considered PMDA Japan approved product as innovator wherein details of dissolution specifications have not been revealed hence we follow the general pharmacopeial guideline for dissolution specifications and parameters for immediate release tablets. Moreover the product approved</td></tr>
</table>

		by USFDA containing vonoprazan is a combo pack product while the applied product formulation is single unit tablet of vonprazan
3.2.P.8	• Submit stability study data of applied product at 6th month time point • Submit copy of clearance certificate or commercial invoice attested by AD (I&E) DRAP. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required	• Stability study data of applied product at 6th month time point is submitted. • Firm has submitted copy of Form 6 dated 27-05-2022 for import of 500g Vonoprazan fumarate in name of M/s Wimits Pharmaceuticals Pvt. Ltd., Lahore attested by AD (I&E) DRAP Lahore dated 27-05-2022. *However copy of clearance certificate or ADC attested commercial invoice is not submitted.* • Audit trail reports on product testing is submitted.

Decision: Deferred for submission of following:

- **Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin**
- **Clarification for submitting details of different brand in pharmaceutical equivalence than that submitted in dossier**
- **Reconciliation of the drug substance as the same Form 6 of API has been submitted as was presented earlier in registration application of "Acvon tablets" by way of contract manufacturing from M/s Wimits Pharmaceutials, which were deferred in 333rd meeting of Registration Board.**

213.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals Pvt. Ltd., Plot No# 129, Sunder Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals Pvt. Ltd., Plot No# 129, Sunder Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 08-09-2021 based on inspection conducted on 08-09-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-51/2004-Lic dated 07-02-2014 which specifies Tablet (General Human) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy. No 27747 dated 30-09-2022
	Details of fee submitted	Rs.30,000/- dated 23-09-2022 (Deposit slip#576967055)
	The proposed proprietary name / brand name	**Vozan 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan as Fumarate……20mg

	Pharmaceutical form of applied drug	Oral solid Tablet
	Pharmacotherapeutic Group of (API)	Potassium Competitive acid blocker (P-CAB)
	Reference to Finished product specifications	In house specifications
	Proposed Pack size	1x10's, 2x10's, 2x7's, 3x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab 20mg tablet by M/s Takeda Pharmaceutical Company Limited, PMDA Japan Approved.
	For generic drugs (me-too status)	Vocinti Tablet 20mg by M/s The Searle Company Limited, (Reg. No. 108836)
	Name and address of API manufacturer.	M/s Enantiotech Corporation Limited., No.6 Zhongjing RD, Zhongshan Torch Hi-Tech Industrial Development Zone, Guangdong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the comparator product that is Vonnp 20mg Tablet, by performing quality tests (Identification, Assay, Dissolution).

		CDP has been performed against the comparator product vonoprazan 20mg Tablet in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including linearity and range, accuracy, precision (Repeatability, Intermediate), specificity, robustness and system suitability.

STABILITY STUDY DATA			
Manufacturer of API	M/s Enantiotech Corporation Limited., No.6 Zhongjing RD, Zhongshan Torch Hi-Tech Industrial Development Zone, Guangdong Province, China		
API Lot No.	TAK09-220101		
Description of Pack (Container closure system)	Alu-Alu Blister packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	TVM001	TVM002	TVM003
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	25-06-2022	27-06-2022	29-06-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Enantiotech Corporation Limited., Zhongshan Torch Hi-Tech Industrial Development Zone, Guangdong Province, China issued by Zhongshan Medical Association China valid upto 30-12-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 dated 27-05-2022 for import of 500g Vonoprazan fumarate in name of M/s Wimits Pharmaceuticals Pvt. Ltd., Lahore attested by AD (I&E) DRAP Lahore dated 27-05-2022.
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Firm has submitted a copy of valid DML
1.6.5	• Valid cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• The firm has again submitted copy of cGMP certificate of M/s Enantiotech Corporation Limited., No.6 Zhongjing Road, Zhongshan Torch Hi-Tech Industrial Development Zone, Zhongshan City, Guangdong Province, China issued by Guangdong Pharmaceutical Industry Association China valid upto 09-06-2025
3.2.S.4	• Justification shall be submitted for using different chromatographic conditions (wavelength, injection volume, mobile phase) for assay test by drug product manufacturer than that by substance manufacturer • Justification shall be submitted for not performing the test for fumaric acid content in batch analysis of drug substance by drug product manufacturer as recommended by drug substance manufacturer	• Firm has revised chromatographic method as per drug substance manufacturer • Fumaric acid content is performed and revised COA of drug product manufacturer is submitted
3.2.P.2	• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product. **Applied product** / **TAKECAB Tablets 20mg** Vonoprazan Fumarate / Vonoprazan Fumarate Lactose monohydrate, Mannitol, Avicel Ph 101, Klucel, Cross carmellose sodium, sodium starch glycolate, magnesium stearate, Tabcoat white, isopropyl alcohol, purified water / D-mannitol, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, fumaric acid, magnesium stearate, hypromellose, macrogol 6000, titanium oxide, yellow ferric oxide	• Firm has submitted compatibility studies of the drug substance with excipients. • The firm has submitted details of reference product **Name:** Voniza 20mg tablets **Manufacturer:** M/s Hilton Pharma **B No#:** 141606 **Mfg date:** 12-2021 **Exp date;** 12-2023 • However, the brand name mentioned in pharmaceutical equivalence studies was vonnp 20mg tablet • Firm has submitted revised pharmaceutical equivalence report in which test for uniformity of dosage units has been performed. • The firm submitted that the innovator product is Takeda that is not easily available that is why we use the local product which is easily available in the market

	• Details of reference product including manufacturer, batch number, manufacturing and expiry date used in pharmaceutical equivalence studies shall be submitted • Details of comparator product including brand name, manufacturer, batch number, manufacturing and expiry date used in CDP studies shall be submitted • Justification shall be submitted for not performing the tests in pharmaceutical equivalence studies including the tests recommended by innovator product review document (uniformity of dosage units) • Justification shall be submitted for not performing pharmaceutical equivalence and CDP studies against the innovator product	
3.2.P.5	• Justify the variation of dissolution parameters i.e. dissolution medium and time from that recommended by USFDA for the vonoprazan tablets. (use of phosphate buffer pH 6.8 instead of 0.05M acetate buffer pH 4.5, and Q at 30 minutes instead on Q at 15 minutes)	• The firm submitted that we have considered PMDA Japan approved product as innovator wherein details of dissolution specifications have not been revealed hence we follow the general pharmacopeial guideline for dissolution specifications and parameters for immediate release tablets. Moreover the product approved by USFDA containing vonoprazan is a combo pack product while the applied product formulation is single unit tablet of vonprazan
3.2.P.8	• Submit stability study data of applied product at 6th month time point • Submit copy of clearance certificate or commercial invoice attested by AD (I&E) DRAP. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required	• Stability study data of applied product at 6th month time point is submitted. • Firm has submitted copy of Form 6 dated 27-05-2022 for import of 500g Vonoprazan fumarate in name of M/s Wimits Pharmaceuticals Pvt. Ltd., Lahore attested by AD (I&E) DRAP Lahore dated 27-05-2022. *However copy of clearance certificate or ADC attested commercial invoice is not submitted.* • Audit trail reports on product testing is submitted.

Decision: Deferred for submission of following:

- **Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin**
- **Clarification for submitting details of different brand in pharmaceutical equivalence than that submitted in dossier**
- **Reconciliation of the drug substance as the same Form 6 of API has been submitted as was presented earlier in registration application of "Acvon tablets" by way of contract manufacturing from M/s Wimits Pharmaceutials, which were deferred in 333rd meeting of Registration Board.**

214.	Name, address of Applicant / Marketing Authorization Holder	M/s Aptcure (Pvt.) Ltd., 8- Pharma City, 30 km Multan Road, Lahore
	Name, address of Manufacturing site.	M/s Aptcure (Pvt.) Ltd., 8- Pharma City, 30 km Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of routine GMP inspection report dated 18-12-2016 and conclusion of inspection was: Based on the areas inspected, the technical people met and the documents reviewed, and considering the findings of the inspection M/s Aptcure (Pvt.) Ltd., 8-Pharma City, 30 km Multan Road, Lahore was considered to be operating at satisfactory level of compliance with GMP guidelines as per Drug Act, 1976 and rules framed there under
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-17/2004-Lic (Vol-I) dated 06-03-2019 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 26566 dated 20-09-2022
	Details of fee submitted	Rs.30,000/- dated 25-08-2022 (Deposit slip#23275003)
	The proposed proprietary name / brand name	**Aptipride 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Levosulpiride……25mg
	Pharmaceutical form of applied drug	Core Tablet for oral administration
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levopraid 25mg Tablet AIF Italy Approved
	For generic drugs (me-too status)	Levopaid 25mg Tablet by M/s Wimits Pharmaceuticals (Reg.No# 99723)
	Name and address of API manufacturer.	M/s Varahi International., Nr. Old Ruby Coach & Rly. Crossing, Opp Naroda Rly. Station Ahmedabad Gujrat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications,

		analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. (Batches: LC/LSP/180304, LC/LSP/180305, LC/LSP/180306)
	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 study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Levopraid 25mg tablet by M/s Pacific Pharma Pvt. Ltd., by performing quality tests (Description, dissolution, disintegration time, assay). Firm has submitted CDP results of their product against the product Levopraid 25mg tablet by M/s Pacific Pharma Pvt. Ltd., in 0.1M HCl (pH 1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8)
	Analytical method validation/verification of product	Firm has submitted method validation studies including specificity, accuracy, precision (repeatability, intermediate), robustness, stability of analytical solution, linearity, range, limit of detection, limit of quantitation.

STABILITY STUDY DATA	
Manufacturer of API	M/s Varahi International., Nr. Old Ruby Coach & Rly. Crossing, Opp Naroda Rly. Station Ahmedabad Gujrat, India.
API Lot No.	31L01Z2122-019
Description of Pack (Container closure system)	Alu-Alu blister packed in card board unit carton
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LS001	LS002	LS003
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	01-2022	01-2022	01-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Varahi International., Opp; Naroda Rly. Station, NH NO; 8, Naroda, Ahmedabad – 382330, Dist. Ahmedabad, India., issued by Food & Drug Control Administration Gujarat State India valid upto 26-06-2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like UV absorbance data, COA, and summary data sheets etc. (Assay of API by potentiometric titration)
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate dated 08-03-2023 based on inspection conducted on 01-03-2023
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• The firm has submitted copy of cGMP certificate of M/s Varahi International., Opp; Naroda Rly. Station, NH NO; 8, Naroda, Ahmedabad – 382330, Gujarat State, India., issued by Food & Drugs Control Administration Gujarat State India valid upto 16-10-2025

3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for chloride content and sulphated ash in batch analysis of drug substance by drug product manufacturer as performed by drug substance manufacturer • Justification shall be submitted for selecting different limit of assay test in batch analysis of drug substance by drug product manufacturer (98.5% to 101.5%) than drug substance manufacturer (98.5% to 101%)	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted. • Revised COA of Levosulpiride raw material with chloride & sulphated ash test is submitted by drug product manufacturer • The firm submitted that it was a typographical mistake, the corrected assay limit is now mentioned on COA. Moreover the assay of raw material as 99.13% which is within range of drug substance manufacturer's specifications
3.2.P.2	• Similarity factor shall be calculated in CDP studies as the dissolution of the applied product is less than 85% (Less than 70%) in acetate buffer (pH 4.5) and phosphate buffer (pH 6.8) • Justification shall be submitted for not performing pharmaceutical equivalence and CDP studies against the innovator product	• Firm has submitted results of similarity factor (f2) in CDP studies and the results are in acceptable range. • The firm submitted that according to WHO technical report series No.902, if the innovator product is not available in local market, you can select leading brand. In our case Levopraid is the leading brand of Levosulpiride 25mg tablets. Supporting documents are submitted
3.2.P.5	• Justification shall be submitted for selection of the assay method of drug product via UV-Vis spectrophotometer instead of HPLC method • Justification shall be submitted for selection of dissolution parameters i.e. medium, volume, apparatus and rpm (0.1N HCl, 900ml, apparatus 2, 75rpm,) • Justification shall be submitted for not performing weight variation test in batch analysis of drug product as per submitted specifications	• The firm submitted that levosulpiride is sparingly soluble in organic solvents but is soluble in buffer pH 6.8 and it shows maximum absorbance at 291nm using buffer as blank. Moreover this method is precise, accurate and linear. • We tried to perform the assay by using organic solvents and c18 column but could not achieve the satisfactory results. However when we develop any method on HPLC, we will revise our method and immediately transfer to HPLC method. Supporting documents are submitted • The firm submitted that we used these dissolution parameters i.e. medium, volume, apparatus and rpm (0.1N HCl, 900ml, apparatus 2, 75rpm) because these conditions are more appropriate to the in-vivo conditions and we get the reliable readings which are repeatable • Firm has submitted revised COAs of 0 month, 3rd month and 6th month (accelerated and real time)
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• Not submitted

3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Detailed raw data sheet is not submitted • The submitted COA of stability study does not show the time point and storage conditions of stability study	• Firm has submitted copy of invoice for import of 25kg Levosulpride IH in name of M/s Aptcure Private Limited attested by AD (I&E) DRAP Lahore dated 02-12-2021. • Detailed raw data sheet containing calculation details are not submitted • Firm has submitted revised COA of stability study which shows the time point and storage conditions

Decision: Deferred for submission of following:

- **Justification for selection of UV-Vis spectrophotometer method for the Assay test of drug product instead of HPLC method along with literary references.**
- **COA of primary / secondary reference standard including source and lot number shall be provided.**
- **Detailed raw data sheet containing calculation details for stability studies.**

215.	Name, address of Applicant / Marketing Authorization Holder	M/s Hiranis Pharmaceuticals (Pvt.) Ltd., Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi
	Name, address of Manufacturing site.	M/s Hiranis Pharmaceuticals (Pvt.) Ltd., Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 12-11-2021 based on inspection conducted on 05-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-33/2009-Lic dated 07-02-2014 which specifies Tablet (General) section
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23371 dated 18-08-2022
	Details of fee submitted	PKR 75,000/- Dated 11-08-2022 (Deposit slip#977440770996)
	The proposed proprietary name / brand name	**Naprazole 500mg/20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Naproxen (Enteric Coated)……..500mg Esomeprazole as Magnesium Trihydrate (Immediate Release)……20mg
	Pharmaceutical form of applied drug	NSAID and proton pump inhibitor WHO ATC code: M01AE52
	Pharmacotherapeutic Group of (API)	Film coated tablet, containing enteric coated Tablet

	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	VIMOVO 500mg/20mg modified-release tablets MHRA Approved
	For generic drugs (me-too status)	Glomov 500/20mg Tablet by M/s Global Pharmaceuticals (Pvt.) Ltd (Reg#109338)
	Name and address of API manufacturer.	**Naproxen:** M/s Dr. Reddy's Laboratories Limited., INDUSTRIAS QUIMICAS FALCON DE MEXICO S.A DE C.V km 4.5 Carretera Federal Cuernavaca-Cuautla 62578 Jiutepec Morelos Mexico **Esomeprazole:** M/s Metrochem API Private Limited., Unit-I Plot No. 62/C/6 Pipeline Road Phase – I, IDA, Jeedimetla, Quthbullapur (M), Medchal-Malkajgiri (Dist), Telangana (State) India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Naproxen:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. **Esomeprazole:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.

	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Vimovo 500mg/20mgTablet by M/s Astrazeneca Sweden. CDP has been performed against the same product Vimovo 500mg/20mg Tablet by M/s Astrazeneca Sweden in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in phosphate buffer are in acceptable range. The values of f2 factor are not calculated for esomeprazole as it is unstable in acidic media and acetate buffer. The values of f2 factor are not calculated for naproxen as it is enteric coated and not tablet ruptured in acidic media and acetate buffer.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including specificity, system suitability, linearity and range, accuracy, precision, detection limit, quantitation limit and robustness.

STABILITY STUDY DATA

Manufacturer of API	**Naproxen:** Dr. Reddy's Laboratories Limited., INDUSTRIAS QUIMICAS FALCON DE MEXICO S.A DE C.V km 4.5 Carretera Federal Cuernavaca-Cuautla 62578 Jiutepec Morelos Mexico **Esomeprazole:** M/s Metrochem API Private Limited., Unit-I Plot No. 62/C/6 Pipeline Road Phase – I, IDA, Jeedimetla, Quthbullapur (M), Medchal-Malkajgiri (Dist), Telangana (State) India		
API Lot No.	Naproxen: ANMA000361 Esomeprazole: ESM/1810426		
Description of Pack (Container closure system)	Alu Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TF-010120	TF-020120	TF-030120
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	17-01-2020	17-01-2020	17-01-2020

No. of Batches		03
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Esomeprazole:** The firm has submitted copy of cGMP certificate of M/s Metrochem API Pvt. Ltd., Unit-I Plot No. 62/C/6 Pipeline Road Phase – I, IDA, Jeedimetla, Quthbullapur (M), Medchal-Malkajgiri (Dist), Telangana (State) India issued by Drugs Control Administration Government of Telangana India valid upto 26/10/2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Esomeprazole:** Firm has submitted copy of invoice for import of 35kg Esomeprazole Magnesium powder in name of M/s Hiranis Pharmaceuticals attested by AD (I&E) DRAP Karachi dated 25-10-2018 **Naproxen:** Firm has submitted copy of invoice for import of 175kg Naproxen in name of M/s Hiranis Pharmaceuticals attested by AD (I&E) DRAP Karachi dated 02-12-2019
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.4	• You have applied for a new drug product while the applied product is a generic drug product, clarify	• The firm submitted that the application submitted as NCE product and fee submitted accordingly was an innocent mistake from our end since the applied formulation falls under generic category, we gravely regret the inconvenience caused
1.6.5	• Valid GMP certificate / DML of both the Drug Substance manufacturer of Esomeprazole and Naproxen issued by relevant regulatory authority of country of origin is required • Address of manufacturing site of M/s Dr. Reddy's Laboratories Limited., shall be provided	**Esomeprazole:** The firm has submitted copy of cGMP certificate of M/s Metrochem API Pvt. Ltd., Unit-I Plot No. 62/C/6 Pipeline Road Phase – I, IDA, Jeedimetla, Quthbullapur (M), Medchal-Malkajgiri (Dist), Telangana (State) India issued by Drugs Control Administration Government of Telangana India valid upto 12/07/2026 **Naproxen:** Firm has submitted copy of cGMP certificate of M/s Industrias Químicas Falcon de México, S.A. de C.V Km.

		4.5 Carretera Federal Cuernavaca-Cuautla, Civac, C.P. Jiutepec, Morelos, México valid upto 12-04-2026. • Address of the manufacturing site of M/s Dr. Reddy's Laboratories limited is as follows: Industrias Químicas Falcon de México, S.A. de C.V Km. 4.5 Carretera Federal Cuernavaca-Cuautla, 62578 Jiutepec, Morelos, México. The firm submitted that Dr. Reddy's Laboratories limited is administrative headquarters and Industrias Quimicas Falcon de Mexico is their manufacturing site. This clarification is mentioned in the 3.2.S.2.1 of DMF. 3.2.S.2.1 of DMF has mentioned that Industrias Quimicas Falcon de Mexico, S.A. . de C.V is subsidiary of Dr. Reddy's Laboratories Limited.
3.2.P.2	• Justification shall be submitted for not performing the test for uniformity of dosage unit in pharmaceutical equivalence studies as recommended by innovator product	• The firm has submitted revised pharmaceutical studies in which test for uniformity of dosage unit has been performed.
3.2.P.5	• The dissolution time of naproxen at buffer phase (Q after 45min instead of Q at 60min) of finished product specification is different than that of innovator product review document, clarify • The dissolution parameters i.e. volume and rpm (1000ml and 50rpm instead of 475ml and 75rpm) for naproxen at acid stage is different than that of innovator product review document, clarify • The dissolution parameters i.e. volume, rpm and time (1000ml, 50rpm, 45min instead of 900ml, 75rpm and 60min) for naproxen at buffer stage is different than that of innovator product review document, clarify	• The firm submitted that we have used Q after 45 minutes instead of 60 minutes on the basis of USP dissolution chapter <711>, for delayed release dosage forms • The firm submitted that we have used the dissolution parameter for naproxen at acid and buffer stage as 1000ml,50 rpm on the basis of FDA updated dissolution information as per FDA dissolution database as innovator also approved by FDA. https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Registration letter will be issued after submission of:

- **Revised dissolution specifications of Naproxen in buffer phase (Q at 60min) in finished product specification**
- **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

216.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt) Ltd., Plot No.35-A, Small Industrial Estate, Taxila,
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd., Plot No.35-A, Small Industrial Estate, Taxila,

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 17-08-2022 based on inspection conducted on 16-08-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-17-2012-Lic dated 26-04-2017 which specifies Cream/Ointment/Gel Section (General)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 27410 dated 27-09-2022
	Details of fee submitted	Rs.75,000/- dated 26-09-2022 (Deposit slip#612399401)
	The proposed proprietary name / brand name	**Remulin Ointment (1% w/w)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram of ointment Contains: Retapamulin……10mg (1% w/w)
	Pharmaceutical form of applied drug	Other antibiotics for topical use
	Pharmacotherapeutic Group of (API)	Semi-Solid Dosage form (Ointment)
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ALTABAX (retapamulin ointment) 1%, for topical use USFDA Approved
	For generic drugs (me-too status)	Pamulin Ointment by Pharmatec Pakistan (Pvt) Ltd., (Reg# 76684)
	Name and address of API manufacturer.	M/s Sumar Biotech LLP., Plot No# 112, 113, 114 GIDC Estate Gozariva Tal. & Dist: Mehsana-382825, Gujarat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form,

		manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product ALTABAX ointment 1% w/w by M/s GlasxoSmithKline.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including specificity, linearity and range, accuracy, precision, detection limit, quantitation limit and robustness.

STABILITY STUDY DATA			
Manufacturer of API	M/s Sumar Biotech LLP., Plot No# 112, 113, 114 GIDC Estate Gozariva Tal. & Dist: Mehsana-382825, Gujarat, India.		
API Lot No.	SBL/SRD/RTP/19/08/061		
Description of Pack (Container closure system)	Aluminium tube which sealed with aluminium seal and capped with screw plastic cap packed in standard unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	RTP-001	RTP-002	
Batch Size	500 Packs	500 Packs	
Manufacturing Date	03-2022	03-2022	
Date of Initiation	01-04-2020	01-04-2020	
No. of Batches	02		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Sumar Biotech LLP., Plot No# 112, 113, 114 GIDC Estate Gozariva Tal. & Dist: Mehsana-382825, Gujarat, India issued by Food & Drugs Control Administration Gujarat State India valid upto 06-10-2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 for import of 200gm+100mg Retapamulin IH with WRS in name of M/s Horizon Healthcare (Pvt.) Ltd., attested by AD (I&E) DRAP Islamabad dated 12-02-2022
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.4	• You have applied for a new drug product while the applied product is a generic drug product, clarify	• The firm submitted that we have applied as new drug product because no local brand available in Pakistan.
1.6.5	• Valid GMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• The firm has submitted copy of cGMP certificate of M/s Sumar Biotech LLP., Plot No# 112, 113, 114 GIDC Estate Gozaria Tal. & Dist: Mehsana-382825, Gujarat, India issued by Food & Drugs Control Administration Gujarat State India valid upto 17-10-2024.
2.3.R.1	• You have submitted BMR and stability study data of only two batches. At least 3 batches having scientifically rational batch size, sufficient enough to perform complete testing till the claimed shelf life is required	• The firm submitted that we have selected two batches as per minutes of 293rd meeting of registration board, implementation of common technical document, 3.2.P.8 stability clause (a), Aerosol and any other specialized preparations 500.
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. • Analytical method validation of retapamulin ointment is submitted instead of Analytical Method Verification studies of retapamulin drug substance. Analytical Method Verification studies including specificity, accuracy and repeatability (method precision)	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for Retapamulin drug substance is submitted.

	performed by the Drug Product manufacturer for drug substance is required.	
3.2.S.7	• Stability study data of drug substance at real time conditions till claimed shelf life shall be submitted	• The firm has submitted the updated stability study data of drug substance conducted at real time conditions 30°C ± 2°C / 65% ± 5% RH till 48 months
3.2.P.5	• Protocol for analytical method validation studies shall be submitted	• Protocol for analytical method validation studies has been submitted
3.2.P.8	• Submit clearance certificate or commercial invoice attested by AD (I&E) DRAP field office. • Submit stability study data of applied product at 6th month time point	• Clearance certificate or commercial invoice is not submitted. The firm has submitted copy of goods declaration letter • Stability study data of applied product at 6th month time point is submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

217.	Name, address of Applicant / Marketing Authorization Holder	M/s Siza International (Pvt.) Ltd., 18 Km, Ferozpur Road, Lahore, Pakistan
	Name, address of Manufacturing site.	M/s Siza International (Pvt.) Ltd., 18 Km, Ferozpur Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-53/85-Lic(Vol-III) dated 18-12-2015 which specifies Dry Powder Suspension (General) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 23367 dated 18-08-2022
	Details of fee submitted	Rs.30,000/- dated 28-02-2022 (Deposit slip#695090765)
	The proposed proprietary name / brand name	**Ulcenil Dry Suspension 40mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml After Reconstitution Contains: Famotidine…….40mg
	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Anti-Ulcerative

	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PEPCID (40mg/5ml) for oral suspension, USFDA Approved ***Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons*****
	For generic drugs (me-too status)	Apsin 40mg/5ml Dry Suspension by M/s Saffron Pharmaceuticals., (Reg#96458)
	Name and address of API manufacturer.	M/s SMS Pharmaceuticals Limited., Unit-IV, Plot No. 66/B-Phase 1, I.D.A, Jeedimetla Hyderabad-500055 Andhra Pradesh India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted

	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including specificity, accuracy, precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s SMS Pharmaceuticals Limited., Unit-I, Plot No. 66/B-Phase 1, I.D.A, Jeedimetla Hyderabad-500055 Andhra Pradesh India.		
API Lot No.	FMT3520821		
Description of Pack (Container closure system)	Amber glass bottle		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	T1	T2	T3
Batch Size	20kg For 60ml;392 bottles For 120ml;392 bottles	20kg For 60ml;392 bottles For 120ml;392 bottles	20kg For 60ml;392 bottles For 120ml;392 bottles
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	19-10-2021	19-10-2021	19-10-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s SMS Lifesciences India Limited., Unit-I, Plot No. 180/2, Kazipalli (V), Jinnaram (M), Sangareddy District, Telangana-502319, India issued by Drugs Control Administration Govt. of Telangana India valid upto three years from the date of issue (Date of issue 09-08-2019)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form commercial invoice for import of 200kg Famotidine USP in name of M/s Siza International (Pvt.) Ltd., attested by AD (I&E) DRAP Lahore dated 09-09-2021
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.6.5	• Valid GMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • Address of API manufacturer mentioned in section 1.6.5 is different than that given in submitted GMP certificate, clarify
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is required.
3.2.P.1	• Provide information including type of diluent, its composition, quantity or volume, specifications and regulatory status in Pakistan for the diluent which is to be provided along with the applied drug.
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product • Justification is required as tests for antimicrobial preservative content and efficacy of preservative are not performed • Pharmaceutical equivalence studies against the innovator/reference product shall be submitted
3.2.P.5	• Clarify the batch size mentioned in batch analysis of finished drug product (20kg, For 60ml;392 bottles, For 120ml;392 bottles)
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• You have mentioned batch size of applied product in stability summary sheets as "For 60ml;392 bottles, For 120ml;392 bottles", clarify • Submit stability study data of applied product at 6th month time point • In use stability study of reconstitution suspension shall be submitted

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

218.	Name, address of Applicant / Marketing Authorization Holder	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 25-06-2019 specifying Sachet General Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 25514 dated 08-09-2022
	Details of fee submitted	Rs.30,000/- dated 12-05-2022 (Deposit slip#15669313366)
	The proposed proprietary name / brand name	**Cadotril Sachet 10mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Racecadotril……..…10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Anti-secretory enkephalinase inhibitor
	Reference to Finished product specifications	Not Applicable (Product is JPL)
	Proposed Pack size	16 Sachets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec Infants 10mg, Granules for oral suspension MHRA Approved
	For generic drugs (me-too status)	Hidrasec 10mg Sachet by M/s Abbott Laboratories (Reg. No# 87082)
	Name and address of API manufacturer.	M/s Symed Labs Limited., India, 8-2-293/174/3, Beside BN Reddy Colony, Road No. 14, Banjara Hills, Hyderabad-500034, Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.

	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.		
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted		
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including Accuracy, Precision, Specificity, linearity, LOD, LOQ, robustness.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Symed Labs Limited., India, 8-2-293/174/3, Beside BN Reddy Colony, Road No. 14, Banjara Hills, Hyderabad-500034, Telangana, India.		
API Lot No.		2KA0100519		
Description of Pack (Container closure system)		**White granular powder with characteristic apricot odor for oral suspension filled in a unit dose sachet, finally packed in a bleach board unit carton.**		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T-01	T-02	T-03
Batch Size		5000 Sachet	5000 Sachet	5000 Sachet
Manufacturing Date		10-2021	10-2021	10-2021
Date of Initiation		27-10-2021	28-10-2021	29-10-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate in the name of M/s Symed Labs Limited., Plot No. 25/B, Phase-III, IDA, Jeedimetla (V), Quthbullapur (M), Medchal - Malkajgiri District, Telangana State, India., issued by Drugs Control Administration Telangana State India valid upto 03-03-2022.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm submitted Letter No. 633/2020/DRAP-AD-CD(I&E) dated 13-01-2020 for "permission to Import API as per guidelines for import of pharmaceutical raw		

		material for the purpose of test/analysis and stability studies" containing Racecadotril 15gm issued by AD (I&E) DRAP Lahore
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)
1.3.5	• Submit GMP certificate / GMP inspection report of the applicant conducted with in last three years
1.5.5	• Indicate Pharmacological class of the API (drug substance) with proper reference
1.5.6	• Clarification is required for term "***Product is JPL***" in Pharmacopoeial Status of applied formulation
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • Address of API manufacturer mentioned in section 1.6.5 is different than that given in submitted GMP certificate
3.2.S.4	• The drug substance manufacturer has selected gradient chromatographic method for assay of drug substance upto 50 minutes while you have selected gradient chromatographic method only upto 35 minutes, clarify. • Provide results of analysis of relevant batch of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacturer.
3.2.P.2	• Pharmaceutical equivalence studies against the innovator/reference product shall be submitted
3.2.P.5	• The applied product is racecadotril sachet while test for identification and assay for strontium ranelate is mentioned in specification, clarification is required. • Submit complete analytical methods for all the tests mentioned in finished product specifications
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Submit documents for procurement of API with approval from DRAP • Submit real time stability data documents including chromatograms, Raw data sheets, COA of applied product

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

219.	Name, address of Applicant / Marketing Authorization Holder	M/s Davis Pharmaceutical Laboratories., Plot No. 121, Industrial Triangle, kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Davis Pharmaceutical Laboratories., Plot No. 121, Industrial Triangle, kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 15-02-2022 based on inspection conducted on 02-02-2022

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.1-22/95-Lic (Vol-II) dated 20-11-2015 specifying Capsule General Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 23275 dated 17-08-2022
	Details of fee submitted	Rs.30,000/- dated 26-11-2021 (Deposit slip#1597194661)
	The proposed proprietary name / brand name	**Dexalan 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole……30mg
	Pharmaceutical form of applied drug	Hard Gelatin Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	**Manufacturer's Specifications**
	Proposed Pack size	3x10' s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	DEXILANT (30mg, 60mg) delayed-release capsules USFDA Approved
	For generic drugs (me-too status)	Dextop Capsule 30 mg by M/s The Searle Company Ltd. (Reg#86978)
	Name and address of API manufacturer.	**Source of pellets:** M/s Vision Pharmaceuticals Pvt. Ltd., Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at

	(Conditions & duration of Stability studies)	40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	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 study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Wilsop 30mg capsule by M/s Wilson's Pharmaceuticals. CDP has been performed against the same product Wilsop 30mg capsule by M/s Wilson's Pharmaceuticals in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including Accuracy, Repeatability, intermediate Precision, robustness, linearity.

STABILITY STUDY DATA

Manufacturer of API	**Source of pellets:** M/s Vision Pharmaceuticals Pvt. Ltd., Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan.		
API Lot No.	DLP664		
Description of Pack (Container closure system)	**Alu-alu blister packed in unit carton**		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-015	T-016	T-017
Batch Size	5000 capsule	5000 capsule	5000 capsule
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	01-2021	01-2021	01-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted copy of cGMP certificate of M/s Vision Pharmaceuticals issued on 31-07-2019 based on inspection conducted on 11-02-2019. The firm have submitted copy of DML of M/s Vision Pharmaceuticals (Pvt) Ltd., renewed w.e.f. 02-12-2019.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice dated 04-12-20 for purchase of 4kg of Dexlansoprazole DDR Pellets 22.5% from M/s Vision Pharmaceuticals Islamabad.
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)
1.5.2	• Submit your label claim as per reference formulation considering the dual delayed release nature of pellets along with submission of applicable fee
1.6.5	• Valid GMP certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is required.
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product (content uniformity and loss on drying). • Details of comparator/reference product including batch number, manufacturing date, expiry date against which pharmaceutical equivalence and CDP studies is performed hall be submitted
3.2.P.5	• Justification is required as the tests of content uniformity and loss on drying are not included in the submitted specifications as recommended by innovator product review document. • Results of specificity test, system suitability, LOD and LOQ in analytical method validation studies are not submitted

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

220.	Name, address of Applicant / Marketing Authorization Holder	M/s Davis Pharmaceutical Laboratories., Plot No. 121, Industrial Triangle, kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Davis Pharmaceutical Laboratories., Plot No. 121, Industrial Triangle, kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 15-02-2022 based on inspection conducted on 02-02-2022

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.1-22/95-Lic (Vol-II) dated 20-11-2015 specifying Capsule General Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 23276 dated 17-08-2022
	Details of fee submitted	Rs.30,000/- dated 26-11-2021 (Deposit slip#92167515)
	The proposed proprietary name / brand name	**Dexalan 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole……60mg
	Pharmaceutical form of applied drug	Hard Gelatin Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	3x10' s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	DEXILANT (30mg, 60mg) delayed-release capsules USFDA Approved
	For generic drugs (me-too status)	Dextop Capsule 60mg by M/s The Searle Company Ltd. (Reg#086979)
	Name and address of API manufacturer.	**Source of pellets:** M/s Vision Pharmaceuticals Pvt. Ltd., Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated

		stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Wilsop 60mg capsule by M/s Wilson's Pharmaceuticals. CDP has been performed against the same product Wilsop 60mg capsule by M/s Wilson's Pharmaceuticals in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including Accuracy, Repeatability, intermediate Precision, robustness, linearity.

STABILITY STUDY DATA			
Manufacturer of API	**Source of pellets:** M/s Vision Pharmaceuticals Pvt. Ltd., Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan.		
API Lot No.	DLP664		
Description of Pack (Container closure system)	**Alu-alu blister packed in unit carton**		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-018	T-019	T-020
Batch Size	5000 capsule	5000 capsule	5000 capsule
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	01-2021	01-2021	01-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted copy of cGMP certificate of M/s Vision Pharmaceuticals issued on 31-07-2019 based on inspection conducted on 11-02-2019. The firm have submitted copy of DML of M/s Vision Pharmaceuticals (Pvt) Ltd., renewed w.e.f. 02-12-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice dated 04-12-20 for purchase of 4kg of Dexlansoprazole DDR Pellets 22.5% from M/s Vision Pharmaceuticals Islamabad.
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)
1.5.2	• Submit your label claim as per reference formulation considering the dual delayed release nature of pellets along with submission of applicable fee
1.6.5	• Valid GMP certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is required.
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product (content uniformity and loss on drying). • Details of comparator/reference product including batch number, manufacturing date, expiry date against which pharmaceutical equivalence and CDP studies is performed hall be submitted
3.2.P.5	• Justification is required as the tests of content uniformity and loss on drying are not included in the submitted specifications as recommended by innovator product review document. • Results of specificity test, system suitability, LOD and LOQ in analytical method validation studies are not submitted
3.2.P.8	• Date of manufacturing of trial batches as per submitted summary sheets is 02-2021 while date of initiation of stability study is 01-2021, clarify?

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

Case No. 02: Registration applications of New Section of Human drugs on Form 5-F (Local)

M/s Siam Pharmaceuticals., 217, Industrial Triangle, Kahuta Road, Islamabad

The Central Licensing Board in its 285th meeting held on 17th & 18th March, 2022 has considered and approved the following additional section of M/s Siam Pharmaceuticals., 217, Industrial Triangle, Kahuta Road, Islamabad., under Drug Manufacturing License No. 000711 (Formulation) vide approval letter No. F. 1-36/2010-Lic (Vol-I) dated 26th May 2022.

S No.	Section
1	Sachet (General) Section

2	Finished Goods Sore (Revised)

Following applications have been submitted for registration by the firm.

221.	Name, address of Applicant / Marketing Authorization Holder	M/s Siam Pharmaceutical., Plot # 217, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Siam Pharmaceutical., Plot # 217, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 17-10-2022 issued based on inspection conducted on 26-01-2022
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-36/2010-Lic (Vol-I) dated 26th May 2022 specifying Sachet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 26043 dated 27-10-2023
	Details of fee submitted	Rs.30,000/- dated 24-10-2023 (Slip#192249834)
	The proposed proprietary name / brand name	**Cellkast 4mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Montelukast Sodium Eq. to Montelukast……4mg
	Pharmaceutical form of applied drug	Granules
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SINGULAIR 4mg oral granules USFDA Approved
	For generic drugs (me-too status)	Montika 4mg Sachet by M/s Sami Pharmaceuticals (Reg#50744)
	Name and address of API manufacturer.	M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., Jiangkou Development Zone, Huangyan, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug

		substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 36 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	CDP has been performed against the product Myteka 4mg Sachet by M/s Hiton Pharma in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, accuracy and precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., Jiangkou Development Zone, Huangyan, Taizhou City, Zhejiang Province, China.		
API Lot No.	11031-220404		
Description of Pack (Container closure system)	White to off white granular powder filled in Megi paper foil further packed in bleach board carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	MK04T004	MK04T005	MK04T006
Batch Size	840 sachet	840 sachet	840 sachet
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	09-2022	09-2022	09-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of	The firm has submitted copy of cGMP certificate of M/s

	API manufacturer issued by concerned regulatory authority of country of origin.	Zhejiang Tianyu Pharmaceutical Co., Ltd., No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China issued by China Food and Drug Administration valid till 14-03-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted	• The firm has submitted copy of DML#Zhe 20050431 of M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China valid till 16-06-2025
3.2.S.4	• Clarification is required as drug product manufacturer has submitted specification of Vortioxetine HBr instead of Montelukast Sodium • The time point and ratio of mobile phase selected for gradient program in assay test of drug substance is different than USP monograph, clarify • Results of specificity test in analytical method verification studies is not submitted. • Submit Certificate of Analysis of the same batch of drug substance used during product development and stability studies from Drug Substance manufacturer.	• Firm has submitted specification of Montelukast Sodium • Firm has submitted revised analytical method for assay test as per USP monograph • Firm has submitted results of specificity test in analytical method verification studies • COA of relevant batch of drug substance from drug substance manufacturer is submitted
3.2.P.2	• Pharmaceutical equivalence studies against the innovator/reference product shall be submitted • Details of innovator/comparator product including batch number, manufacturing date, expiry date against which CDP studies is performed shall be submitted	• Firm has submitted pharmaceutical equivalence of their product against the product Myteka 4mg sachet by M/s Hilton Pharma. • Details of comparator product is submitted Btach#144293, Mfg date; 06-2022, Exp date; 06-2024
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications as per USP monograph	• Firm has submitted the results of uniformity of dosage units test
3.2.P.6	• Clarification is required since the submitted COA of reference / working standard states that it follows in house specifications while the product monograph is available in USP	• Firm has submitted another COA of working reference standard and it follows USP specifications • The firm submitted that as per claimed

	• You have submitted COA of Montelukast sodium working reference standard while USP monograph recommends the use of Montelukast Dicyclohexylamine as reference standard in analytical method, clarify	composition we can use montelukast sodium as working reference standard because we are concerned about montelukast not sodium and dicyclohexylamine
3.2.P.8	• Stability study data at 6th month time point is not submitted • The batch number of API mentioned in stability summary sheets (11002-220305) is different than that submitted in batch analysis of drug substance (11031-220404) clarify • Documents for the procurement of API with approval from DRAP (in case of import).	• Stability study data at 6th month time point is submitted • Firm has submitted batch analysis of API batch# 11002-220305 • Firm has submitted copy of clearance certificate for import of 10kg Montelukast Sodium USP (Batch#11031-220404) in name of M/s Siam Pharmaceuticals., attested by AD (I&E) DRAP Islamabad dated 23-08-2022. Clearance certificate of different batch No. of API is submitted

Decision: Deferred for submission of following:

- **Clarification for using Montelukast sodium working standard in analytical method instead of Montelukast Dicyclohexylamine as reference standard as recommended by USP monograph.**
- **Clearance certificate or commercial invoice attested by AD (I&E) DRAP of relevant batch of API used for manufacturing of drug product stability batches.**

Case No. 03: Registration applications of New Section of Human drugs on Form 5-F (Local)

M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha.

The Central Licensing Board in its 276th meeting held on 3rd September, 2020 has considered and approved the following additional section of M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha., under Drug Manufacturing License No. 000609 (Formulation) vide approval letter No. F. 1-37/2003-Lic (Vol-I) dated 29th September 2020.

S No.	Section
1	Capsule (General) Section (New)
2	Sachet (General) Section (New)

Following applications have been submitted for registration by the firm.

222.	Name, address of Applicant / Marketing Authorization Holder	M/s Quaper (Pvt.) Ltd., 26-A, Small Industrial Estate, Lahore Road, Sargodha.
	Name, address of Manufacturing site.	M/s Quaper (Pvt.) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 19-06-2019 issued based on inspection conducted on 28-01-2019
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-37/2003-Lic (Vol-I) dated 29th September 2020 specifying Capsule (General) Section (New).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23862 dated 28-09-2023
	Details of fee submitted	PKR 30,000/-: dated 25-09-2023 (Deposit slip#4189067313)
	The proposed proprietary name / brand name	**PREGAL 150mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Pregabalin……150mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Antiepileptics, other antiepileptic
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg) Capsule USFDA Approved
	For generic drugs (me-too status)	Zeegap 150mg Capsule by M/s Hilton Pharmaceuticals (Reg# 47361)
	Name and address of API manufacturer.	M/s Progress Life Sciences Pvt. Ltd., Unit-III, Plot No. 23&24, Jawaharlal Nehru Pharma City, Thanam (V), Parawada (M), J-311,Bhosari MIDC, Pune - 400 026 Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	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 study.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Lyrica 150mg Capsule. CDP has been performed against the same product Lyrica 150 mg Capsule in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including specificity, Accuracy, Precision

STABILITY STUDY DATA

Manufacturer of API	M/s Progress Life Sciences Pvt. Ltd., Unit-III, Plot No. 23&24, Jawaharlal Nehru Pharma City, Thanam (V), Parawada (M), J-311,Bhosari MIDC, Pune - 400 026 Maharashtra, India		
API Lot No.	PPR/21006		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 Cap	1500 Cap	1500 Cap
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	15-02-2023	16-02-2023	17-02-2023
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of M/s Morepen Laboratories Limited., Village Masulkhana, Parwanoo, Distt. Solan (H.P), India issued by Health and Family Welfare Department Himachal Pradesh India valid upto 11-05-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm submitted that they have received loan of API from M/s Biomark Pharmaceuticals and submitted copy of commercial invoice for import of 25kg Pregabalin attested by AD (I&E) DRAP Lahore dated 25-06-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm submitted that HPLC software is 21 CFR compliant and submitted certificate of compliance. The firm submitted that audit trial has not been activated

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.5	• Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate dated 22-08-2022 issued based on inspection conducted on 16-08-2022
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted as the submitted GMP certificate is of different manufacturer	• Firm has submitted copy of cGMP certificate of M/s Progress Life Sciences Pvt. Ltd., Unit-III, Plot No. 23&24, Jawaharlal Nehru Pharma City, Thanam (V), Parawada (M), J-311,Bhosari MIDC, Pune - 400 026 Maharashtra, India issued by Food & Drugs Administration Maharashtra State India valid upto 13-06-2024
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Drug substance manufacturer have claimed for EP specification while selected different limited of assay test (95-105%) than EP monograph (98-102%). Clarification is required • Clarification is required as drug substance manufacturer has claimed for EP specification while drug product manufacturer has claimed USP specifications and used different chromatographic conditions for assay test • Clarification is required as drug substance manufacturer has submitted specification as per EP while batch analysis as per USP • Clarification is required as drug product manufacturer has submitted limits of Enantiomeric purity as NMT 0.15% and results as 99.97% and Assay limits as 98.0-102% and results complies in batch analysis	• The firm submitted that as pregabalin was not present in the old version of USP or BP, so the API manufacturer had set the specifications as per EP general monograph and In-house specifications. Now the monograph of pregabalin is present in the USP and the material imported for product development was according to USP specifications. The raw material specification of API is according to USP and the assay limit is 98% - 102%. The results of API analysis were in concordant with both assay limits, i.e. (95%-105%) and (98%-102%). • As pregabalin was not present in the old version of USP or BP, so the API manufacturer had set the specifications as per EP general monograph and In-house specifications. Now the monograph of pregabalin is present in the USP and the material imported for product development was according to USP specifications. The chromatographic conditions are same as defined in the individual monograph of Pregabalin. The certificate of analysis of raw material also depicts that material imported is according to USP. • As pregabalin was not present in the old version of USP or BP, so the API manufacturer had set the specifications as per EP general monograph and In-house specifications. Now the monograph of pregabalin is present in the USP. So the API's certificate of analysis is as per USP.

		• The result 99.97% given in the certificate of analysis by drug product manufacturer is actually the result of assay, which is mistakenly misplaced with enantiomeric impurity due to typographic mistake. This result is within the assay limit of 98.0% – 102.0%.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of working standard including source and lot number is submitted.
3.2.P.2	• Details of innovator/comparator product including manufacturer, batch number, manufacturing date, expiry date against which CDP and pharmaceutical equivalence studies is performed shall be submitted	• Details of innovator/comparator product is provided. Product Name: Lyrica 150mg capsule Batch No: 3A03035 Mfg Date: 04/2022 Exp Date: 03/2025 Manufactured by: Pfizer Pakistan
3.2.P.8	• Clarification is required as the manufacturing date mentioned in batch analysis of drug product is 08-2023 while 02-2023 in stability summary sheets • Loan letter for API is not submitted	• The firm submitted that there is a typographic mistake in the certificate of analysis of drug product. The trial batches were manufactured in 02-2023 and stability study was initiated in February 2023. The finished product was tested in 02-2023 but mistakenly 08-2023 was written in CoA. • The firm has submitted copy of loan letter of API from M/s Bio-Mark Pharmaceuticals dated 16-01-2023

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

223.	Name, address of Applicant / Marketing Authorization Holder	M/s Quaper (Pvt.) Ltd., 26-A, Small Industrial Estate, Lahore Road, Sargodha.
	Name, address of Manufacturing site.	M/s Quaper (Pvt.) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 19-06-2019 issued based on inspection conducted on 28-01-2019
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-37/2003-Lic (Vol-I) dated 29th September 2020 specifying Capsule (General) Section (New).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23863 dated 28-09-2023
	Details of fee submitted	PKR 30,000/-: dated 25-09-2023 (Deposit slip#23209631)
	The proposed proprietary name / brand name	**PREGAL 300mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Pregabalin……300mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Antiepileptics, other antiepileptic
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg) Capsule USFDA Approved
	For generic drugs (me-too status)	Zeegap 300mg Capsule by M/s Hilton Pharmaceuticals (Reg# 47364)
	Name and address of API manufacturer.	M/s Progress Life Sciences Pvt. Ltd., Unit-III, Plot No. 23&24, Jawaharlal Nehru Pharma City, Thanam (V), Parawada (M), J-311,Bhosari MIDC, Pune - 400 026 Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	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 study.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Lyrica 300mg Capsule. CDP has been performed against the same product Lyrica 300 mg Capsule in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including specificity, Accuracy, Precision

STABILITY STUDY DATA

Manufacturer of API	M/s Progress Life Sciences Pvt. Ltd., Unit-III, Plot No. 23&24, Jawaharlal Nehru Pharma City, Thanam (V), Parawada (M), J-311,Bhosari MIDC, Pune - 400 026 Maharashtra, India		
API Lot No.	PPR/21006		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T004	T005	T006
Batch Size	1500 Cap	1500 Cap	1500 Cap
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	15-02-2023	16-02-2023	17-02-2023
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of M/s Morepen Laboratories Limited., Village Masulkhana, Parwanoo, Distt. Solan (H.P), India issued by Health and Family Welfare Department Himachal Pradesh India valid upto 11-05-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm submitted that they have received loan of API from M/s Biomark Pharmaceuticals and submitted copy of commercial invoice for import of 25kg Pregabalin attested by AD (I&E) DRAP Lahore dated 25-06-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm submitted that HPLC software is 21 CFR compliant and submitted certificate of compliance. The firm submitted that audit trial has not been activated

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.5	• Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate dated 22-08-2022 issued based on inspection conducted on 16-08-2022
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted as the submitted GMP certificate is of different manufacturer	• Firm has submitted copy of cGMP certificate of M/s Progress Life Sciences Pvt. Ltd., Unit-III, Plot No. 23&24, Jawaharlal Nehru Pharma City, Thanam (V), Parawada (M), J-311,Bhosari MIDC, Pune - 400 026 Maharashtra, India issued by Food & Drugs Administration Maharashtra State India valid upto 13-06-2024
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Drug substance manufacturer have claimed for EP specification while selected different limited of assay test (95-105%) than EP monograph (98-102%). Clarification is required • Clarification is required as drug substance manufacturer has claimed for EP specification while drug product manufacturer has claimed USP specifications and used different chromatographic conditions for assay test • Clarification is required as drug substance manufacturer has submitted specification as per EP while batch analysis as per USP • Clarification is required as drug product manufacturer has submitted limits of Enantiomeric purity as NMT 0.15% and results as 99.97% and Assay limits as 98.0-102% and results complies in batch analysis	• The firm submitted that as pregabalin was not present in the old version of USP or BP, so the API manufacturer had set the specifications as per EP general monograph and In-house specifications. Now the monograph of pregabalin is present in the USP and the material imported for product development was according to USP specifications. The raw material specification of API is according to USP and the assay limit is 98% - 102%. The results of API analysis were in concordant with both assay limits, i.e. (95%-105%) and (98%-102%). • As pregabalin was not present in the old version of USP or BP, so the API manufacturer had set the specifications as per EP general monograph and In-house specifications. Now the monograph of pregabalin is present in the USP and the material imported for product development was according to USP specifications. The chromatographic conditions are same as defined in the individual monograph of Pregabalin. The certificate of analysis of raw material also depicts that material imported is according to USP. • As pregabalin was not present in the old version of USP or BP, so the API manufacturer had set the specifications as per EP general monograph and In-house specifications. Now the monograph of pregabalin is present in the USP. So the API's certificate of analysis is as per USP.

		• The result 99.97% given in the certificate of analysis by drug product manufacturer is actually the result of assay, which is mistakenly misplaced with enantiomeric impurity due to typographic mistake. This result is within the assay limit of 98.0% – 102.0%.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of working standard including source and lot number is submitted.
3.2.P.2	• Details of innovator/comparator product including manufacturer, batch number, manufacturing date, expiry date against which CDP and pharmaceutical equivalence studies is performed shall be submitted	• Details of innovator/comparator product is provided. Product Name: Lyrica 300mg capsule Batch No: 4A03036 Mfg Date: 04/2022 Exp Date: 03/2025 Manufactured by: Pfizer Pakistan
3.2.P.8	• Clarification is required as the manufacturing date mentioned in batch analysis of drug product is 08-2023 while 02-2023 in stability summary sheets • Loan letter for API is not submitted	• The firm submitted that there is a typographic mistake in the certificate of analysis of drug product. The trial batches were manufactured in 02-2023 and stability study was initiated in February 2023. The finished product was tested in 02-2023 but mistakenly 08-2023 was written in CoA. • The firm has submitted copy of loan letter of API from M/s Bio-Mark Pharmaceuticals dated 16-01-2023

Decision: Approved. Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case No. 04: Registration applications of New Section of Human drugs on Form 5-F (Local)

M/s Saffron Pharmaceuticals (Pvt) Ltd., 19-Km Sheikhupura Road, Faisalabad

The Central Licensing Board in its 275th meeting held on 25 June, 2020 has considered and approved the following additional section of M/s Saffron Pharmaceuticals (Pvt) Ltd., 19-Km Sheikhupura Road, Faisalabad., under Drug Manufacturing License No. 000616 (Formulation) vide approval letter No. F. 1-12/99-Lic (Vol-II) dated 07th July 2020.

S No.	Section
1	Capsule (Cephalosporin)
2	Oral Dry Powder Suspension (Cephalosporin)
3	Dry Powder Injectable (Cephalosporin)

Following applications have been submitted for registration by the firm.

224.	Name, address of Applicant / Marketing Authorization Holder	M/s Saffron Pharmaceuticals (Pvt.) Ltd., 19-Km Sheikhupura Road, Faisalabad.
	Name, address of Manufacturing site.	M/s Saffron Pharmaceuticals (Pvt.) Ltd., 19-Km Sheikhupura Road, Faisalabad.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 25-03-2022 based on inspection conducted on 03-01-2022.
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-12/99-Lic (Vol-II) dated 07th July 2020 specifying Dry Powder Injectable (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 18532 dated 24-07-2023
	Details of fee submitted	Rs.30,000/- dated 19-06-2023 (Slip#691693865537)
	The proposed proprietary name / brand name	**Safpime 500mg IV/IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each combination pack contains: Vial: Cefepime HCl (with L-Arginine) Eq. to Cefepime……500mg Ampoule: Water for injection…….5ml
	Pharmaceutical form of applied drug	Intravenous/Intramuscular
	Pharmacotherapeutic Group of (API)	Cephalosporin-Antibiotics
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's, 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MAXIPIME (500mg, 1g, 2g) for injection USFDA Approved
	For generic drugs (me-too status)	Maxipime 500mg Injection by M/s GSK Pakistan Limited (Reg#25548)
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District: Raigad, Raigad 402302, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its

		verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Maxum 500mg Injection IM/IV by M/s Curexa Health Pvt. Ltd. (Highnoon Laboratories Ltd.)
	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, linearity and range, accuracy, precision, detection limit, quantitation limit, system suitability.

STABILITY STUDY DATA

Manufacturer of API	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District: Raigad, Raigad 402302, Maharashtra India.		
API Lot No.	CEIV/B2012114		
Description of Pack (Container closure system)	Filled and sealed glass vial packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	500 vial	500 vial	500 vial
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	09-02-2022	09-02-2022	09-02-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.., issued by Commissioner, Food & Drugs Administration Maharashtra State India valid upto 19-10-2023

		Firm has submitted copy of License retention certificate of M/s Kopran Research Laboratories Limited., India., issued by Food & Drugs Administration Maharashtra State India valid upto 31-03-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm submitted Letter No. 10153/2020/DRAP-AD-VII(I&E) dated 27-07-2020 for "permission to Import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability studies" containing Cefepime HCl 02kgm issued by AD (I&E) DRAP Lahore
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's Response
1.5.2	• The applied label claim shall include only description of dry powder injection only, while for diluent separate registration application shall be applied	• The firm submitted that our formulation is IV Injection, the diluent used with injection is WFI. Registration letter of WFI is submitted
1.5.10	• Dosage form of applied drug shall be mentioned clearly, with complete description of a unit	• Sterile powder for injection
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted	• Firm has again submitted copy of License retention certificate of M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Birwadi, Mahad-402302,, District: Raigad, India., issued by Food & Drugs Administration Maharashtra State India valid upto 31-03-2025.
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification is required for not performing test for Arginine content in batch analysis by drug product manufacturer as recommended by drug substance manufacturer • Justification shall be submitted for selecting the limit of water content test as 8.0%-11.0% in batch analysis instead of NMT 4.0 % by drug product manufacturer as per drug substance manufacturer specifications	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies is not submitted • As the material complies with USP specifications, arginine test is not performed in USP. That's why arginine test was not performed by the manufacturer. USP monograph is submitted • The firm submitted that corrected limit is NMT 4% & revised COA is submitted
3.2.P.8	• Clarification shall be submitted, as the batch size mentioned in BMR is 500vials while 300vials in stability summary sheets.	• The firm submitted that batch size of 500 vials was prepare in which 300 vials were placed for

	• Justify the delay between manufacturing of trial batches (12-2021) and initiation of stability studies (09-02-2022.). • Submit AD (I&E) DRAP attested commercial invoice or clearance certificate for the procurement of API. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Justify the results of assay test based on a single chromatographic area	stability testing, while 200 vials were placed as reference sample • The firm submitted that delay occurred due to non-availability of reference standard for standardization of testing procedure • The firm submitted Letter No. 10153/2020/DRAP-AD-VIII(I&E) dated 27-07-2020 for "permission to Import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability studies" containing Cefepime HCl 02kg issued by AD (I&E) DRAP Lahore dated 24-07-2020. However, no invoice or clearance certificate is submitted • Audit trail reports on product testing is submitted • As per USP monograph testing of cefepime was carried out. So, the single chromatographic area was observed

Decision: Deferred for submission of following:

- **The applied label claim shall include description of dry powder injection only**
- **Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.**
- **Justification for not performing test for Arginine content in batch analysis by drug product manufacturer as recommended by drug substance manufacturer**
- **Justification for the delay between manufacturing of trial batches and initiation of stability studies**
- **Clearance certificate or commercial invoice attested by AD (I&E) DRAP for the procurement of API.**
- **Justification for the results of assay test based on a single chromatographic area.**

225.	Name, address of Applicant / Marketing Authorization Holder	M/s Saffron Pharmaceuticals (Pvt.) Ltd., 19-Km Sheikhupura Road, Faisalabad.
	Name, address of Manufacturing site.	M/s Saffron Pharmaceuticals (Pvt.) Ltd., 19-Km Sheikhupura Road, Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 25-03-2022 based on inspection conducted on 03-01-2022.
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-12/99-Lic (Vol-II) dated 07th July 2020 specifying Dry Powder Injectable (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 19298 dated 03-08-2023
	Details of fee submitted	Rs.30,000/- dated 19-06-2023 (Slip#518159184555)
	The proposed proprietary name / brand name	**Safpime 1g IV/IM Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each combination pack contains: Vial: Cefepime HCl (with L-Arginine) Eq. to Cefepime……1g Ampoule: Water for injection…….10ml
	Pharmaceutical form of applied drug	Intravenous/Intramuscular
	Pharmacotherapeutic Group of (API)	Cephalosporin-Antibiotics
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's, 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MAXIPIME (500mg, 1g, 2g) for injection USFDA Approved
	For generic drugs (me-too status)	Maxipime 1g Injection by M/s GSK Pakistan Limited (Reg#25549)
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District: Raigad, Raigad 402302, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Maxum 1g Injection IM/IV by M/s Curexa Health Pvt. Ltd. (Highnoon Laboratories Ltd.)
	Analytical method validation/verification of	Firm has submitted method verification studies

	product	including specificity, linearity and range, accuracy, precision, detection limit, quantitation limit, system suitability.

STABILITY STUDY DATA

Manufacturer of API	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District: Raigad, Raigad 402302, Maharashtra India.		
API Lot No.	CEIV/B2012114		
Description of Pack (Container closure system)	Filled and sealed glass vial packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	500 vial	500 vial	500 vial
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	09-02-2022	09-02-2022	09-02-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.., issued by Commissioner, Food & Drugs Administration Maharashtra State India valid upto 19-10-2023 Firm has submitted License retention certificate of M/s Kopran Research Laboratories Limited., India., issued by Food & Drugs Administration Maharashtra State India valid upto 31-03-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm submitted Letter No. 10153/2020/DRAP-AD-VII(I&E) dated 27-07-2020 for "permission to Import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability studies" containing Cefepime HCl 02kgm issued by AD (I&E) DRAP Lahore
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response

1.5.2	• The applied label claim shall include only description of dry powder injection only, while for diluent separate registration application shall be applied	• The firm submitted that our formulation is IV Injection, the diluent used with injection is WFI. Registration letter of WFI is submitted
1.5.10	• Dosage form of applied drug shall be mentioned clearly, with complete description of a unit	• Sterile powder for injection
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted	• Firm has again submitted copy of License retention certificate of M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Birwadi, Mahad-402302,, District: Raigad, India., issued by Food & Drugs Administration Maharashtra State India valid upto 31-03-2025.
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification is required for not performing test for Arginine content in batch analysis by drug product manufacturer as recommended by drug substance manufacturer • Justification shall be submitted for selecting the limit of water content test as 8.0%-11.0% in batch analysis instead of NMT 4.0 % by drug product manufacturer as per drug substance manufacturer specifications	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies is not submitted • As the material complies with USP specifications, arginine test is not performed in USP. That's why arginine test was not performed by the manufacturer. USP monograph is submitted • The firm submitted that corrected limit is NMT 4% & revised COA is submitted
3.2.P.8	• Stability summary sheet for batch No#T-003 at real time conditions is not submitted • Justify the delay between manufacturing of trial batches (12-2021) and initiation of stability studies (09-02-2022.). • Submit AD (I&E) DRAP attested commercial invoice or clearance certificate for the procurement of API. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Justify the results of assay test based on a single chromatographic area	• No reply submitted • The firm submitted that delay occurred due to non-availability of reference standard for standardization of testing procedure • The firm submitted Letter No. 10153/2020/DRAP-AD-VIII(I&E) dated 27-07-2020 for "permission to Import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability studies" containing Cefepime HCl 02kg issued by AD (I&E) DRAP Lahore dated 24-07-2020. However, no invoice or clearance certificate is submitted • Audit trail reports on product testing is submitted • As per USP monograph testing of cefepime was carried out. So, the single chromatographic area was observed

Decision: Deferred for submission of following:

- **The applied label claim shall include only description of dry powder injection only**
- **Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.**
- **Justification for not performing test for Arginine content in batch analysis by drug product manufacturer as recommended by drug substance manufacturer**

- **Justification for the delay between manufacturing of trial batches and initiation of stability studies.**
- **Clearance certificate or commercial invoice attested by AD (I&E) DRAP for the procurement of API.**
- **Justification for the results of assay test based on a single chromatographic area**

Case No. 05: Registration applications of New Section of Human drugs on Form 5-F (Local)

M/s Bio-Labs (Pvt), Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad

The Central Licensing Board in its 282nd meeting held on 31st August, 2021 has considered and approved the following additional section of M/s Bio-Labs (Pvt), Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad., under Drug Manufacturing License No. 000296 (Formulation) vide approval letter No. F. 1-12/89-Lic (Vol-IV) dated 27th September 2021.

S No.	Section
1	Ointment/Gel (Steroid) (in place of licensed Vaccine Veterinary Section)
2	Ointment/Gel (General) (in place of licensed Vaccine Veterinary Section)
3	Lotion (General) (in place of licensed Vaccine Veterinary Section)
4	Dry Vial Injection (General) (Additional Section)

Following applications have been submitted for registration by the firm.

226.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-12/89-Lic (Vol-IV) dated 27th September 2021 specifying Lotion (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 23859 dated 28-09-2023
	Details of fee submitted	Rs.30,000/- dated 21-07-2023 (Slip#647232080)
	The proposed proprietary name / brand name	**Clotrimazole Lotion 1%**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Clotrimazole……1%
	Pharmaceutical form of applied drug	Lotion
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	USP
	Proposed Pack size	60 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LOTRIMIN AF 1% Topical Lotion USFDA Approved

	For generic drugs (me-too status)	Clotri Lotion by M/s Jawa Pharmaceuticals (Reg#88792)
	Name and address of API manufacturer.	M/s Pranami Drugs Pvt. Ltd., Plot No. 7290 GIDC Industrial Estate, Ankleshwar, 393002, Dist. Bharuch, Guj. India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Stiemazol by M/s GlaxoSmithkline Pak Limited.
	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, accuracy and precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Pranami Drugs Pvt. Ltd., Plot No. 7290 GIDC Industrial Estate, Ankleshwar, 393002, Dist. Bharuch, Guj. India.		
API Lot No.	CLZ/0010221		
Description of Pack (Container closure system)	A multicolored 60ml labelled plastic bottle packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CLT 22-151	CLT 22-152	CLT 22-153

Batch Size	150 Bottles	150 Bottles	150 Bottles
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	03-09-2022	03-09-2022	03-09-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice dated 30-03-2021 for import of 25kg of Clotrimazole USP in name of M/s Bio-Labs (Pvt.) Ltd attested by AD (I&E) DRAP Islamabad dated 27-04-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.3.5	• Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate dated 28-12-2023 based on inspection conducted on 09-10-2023.
1.5.2	• Standardize your label claim in line with reference formulation	• The firm has submitted the label claim as **Clotrimazole Lotion 1% w/v** without submission of fee. Each ml Contains: Clotrimazole……10mg
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted	• Firm has submitted copy of cGMP certificate of M/s Pranami Drugs Pvt. Ltd., Plot No. 7209 GIDC Industrial Estate, Ankleshwar, Dist. Bharuch, 393002, India.., issued by Food & Drugs Control Administration Gujarat State India valid upto 19-08-2024
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required.	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is submitted.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of working standard including source and lot number is submitted.
3.2.P.2	• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product. **Applied product** LOTRIMIN AF 1%	• Compatibility studies of the Drug Substance with excipients is submitted

	Clotrimazole Polyethylene Glycol 400	Topical Lotion Clotrimazole Cetearyl alcohol, Cetyl ester wax, otyl dodecanol, polysorbate, sodium biphosphate, sodium phosphate dibasic, sorbitan monostearat, water and as a preservative benzyl alcohol (1%)	
3.2.P.5	• In description of specification you have submitted that it is transparent solution while you have applied for topical lotion, clarification is required	• The firm submitted that the reference product Stiemazol by GSK is lotion having transparent appearance of solution. (Lotion can be as liquid preparation)
3.2.P.8	• Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life	• Total B. size; 150 bottles • For accelerated stability; 28 Bottles • For Real time stability; 84 Bottles • Total packs required for 24 months; 124bottles • Hence the batch size is sufficient for complete testing till shelf life

Decision: Approved with following label claim:
Each ml Contains:
Clotrimazole……10mg

- **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

227.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-12/89-Lic (Vol-IV) dated 27th September 2021 specifying Lotion (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 23858 dated 28-09-2023

	Details of fee submitted	Rs.30,000/- dated 28-08-2023 (Slip#7474686415)
	The proposed proprietary name / brand name	**Biometa 0.1% Lotion (Mometasone Furoate)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	0.1% w/v
	Pharmaceutical form of applied drug	Lotion
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	20ml, 30ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ELOCON 0.1% Lotion, for topical use USFDA Approved ***Discontinued*** ***Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons*** ZATAMIL 0.1% LOTION mometasone furoate 0.1% w/w (1 mg/g) lotion bottle TGA Approved
	For generic drugs (me-too status)	Momate 0.1% Lotion by Maxitech Pharma (Reg#83744)
	Name and address of API manufacturer.	Envee Drugs Pvt. Ltd., N. H. No. 8, Dumral-387 355, Ta. Nadiad, Dist: Kheda, Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Momate 0.1% Lotion by M/s Maxitech Pharma (Pvt.) Limited.

	Analytical method validation/verification of product	Firm has submitted method validation studies including specificity, linearity and range, accuracy, precision (repeatability), system suitability, robustness, Limit of Detection and Limit of Quantitation.

STABILITY STUDY DATA			
Manufacturer of API	M/s Envee Drugs Pvt. Ltd., N. H. No. 8, Dumral-387 355, Ta. Nadiad, Dist: Kheda, Gujarat, India		
API Lot No.	EV/MF-072/19		
Description of Pack (Container closure system)	A PVC bottle packed in multicolored unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MOM22-127	MOM22-128	MOM22-129
Batch Size	150 Bottles	150 Bottles	150 Bottles
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	27-08-2022	27-08-2022	27-08-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Envee Drugs Pvt. Ltd., N. H. No. 8, at & post.-Dumral-387 355, Ta. Nadiad, Dist: Kheda, India issued by Food and Drug Control Administration Gujarat State India., valid till 06-07-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice dated 28-06-2019 for import of 0.5kg of Mometasone Furoate USP in name of M/s Bio-Labs (Pvt.) Ltd attested by AD (I&E) DRAP Islamabad dated 19-07-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.3.5	• Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate dated 28-12-2023 based on inspection conducted on 09-10-2023.
1.5.2	• Clearly indicate the Strength / concentration of Active Pharmaceutical	• The firm has submitted label claim as per reference formulation without submission of

	ingredient per unit in label claim along with submission of applicable fee	applicable fee. The applied label claim is as under: Each gram contains: Mometasone furoate……..1mg
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted	• The firm has submitted copy of cGMP certificate of M/s Envee Drugs Pvt. Ltd., N. H. No. 8, at & post.-Dumral-387 355, Ta. Nadiad, Dist: Kheda, India issued by Food and Drugs Control Administration Gujarat State India., valid till 04-08-2025
3.2.P.5	• In description of specification you have submitted that it is transparent solution while you have applied for topical lotion, clarification is required • Justification shall be submitted for not including the pH test in finished product specifications as per innovator product review document	• The firm submitted that innovator product Elocon lotion and the local market reference product Momate lotion by maxitech pharma, is also in solution form. • Monograph for Mometasone Furoate Topical Solution is available in USP while monograph for Mometasone Furoate Topical lotion is not available in USP • The SAP is updated and pH test is added in finished product specification
3.2.P.8	• 6th month stability study data of batch No# MOM22-128 is not submitted • Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life • Justify the filled volume of applied product as you have mentioned 40ml in executed BMR and 20ml, 30ml in proposed pack size	• 6th month stability study data of batch No# MOM22-128 is submitted • Total batch size; 150 bottles For accelerated stability; 28 bottles For real time stability; 84 bottles Total Packs required for 24 months; 112 bottles. • Hence the batch size is sufficient for complete testing till shelf life. • Fill volume is 20ml, while there is typographic error in BMR

Decision: Approved with following label claim:
Each gram contains:
Mometasone furoate……..1mg

- **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

228.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	**New Section**

		Firm has submitted copy of letter No. F. 1-12/89-Lic (Vol-IV) dated 27th September 2021 specifying Lotion (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 9094 dated 04-04-2023
	Details of fee submitted	Rs.30,000/- dated 29-03-2023 (Slip#056237025)
	The proposed proprietary name / brand name	**Funasole 1% Lotion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Terbinafine HCl……..…1%
	Pharmaceutical form of applied drug	Lotion
	Pharmacotherapeutic Group of (API)	Anti-fungal
	Reference to Finished product specifications	JP
	Proposed Pack size	20ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lamisil lotion 1% Netherland Approved
	For generic drugs (me-too status)	Terbisil Lotion by Saffron Pharmaceuticals (Reg#90109)
	Name and address of API manufacturer.	M/s Shandong Boyuan Pharmaceutical Co., Ltd., Qiangjin Street, Jibei Economic Development Zone, Jinan, Shandong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls,

		specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Terbisil Lotion by M/s Saffron Pharmaceutical Limited.
	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, linearity and range, accuracy, precision (repeatability), system suitability.

STABILITY STUDY DATA

Manufacturer of API	M/s Shandong Boyuan Pharmaceutical Co., Ltd., Qiangjin Street, Jibei Economic Development Zone, Jinan, Shandong, China		
API Lot No.	210617TA		
Description of Pack (Container closure system)	Colorless clear solution in plastic bottle		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRB 22-145	TRB 22-146	TRB 22-147
Batch Size	150 Bottles	150 Bottles	150 Bottles
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	30-08-2022	30-08-2022	30-08-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Shandong Boyuan Pharmaceutical Co., Ltd., No. 12 Taixing East Street, Jibei Economic Development Zone, Jiyang District, Jinan City, Shandong Province, China issued by Center for Assessment of Shandong Pharmaceutical Profession Association China., valid till 06-05-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 10-08-2022 for import of 25kg of Terbinafine HCl JP in name of M/s Bio-Labs (Pvt.) Ltd attested by AD (I&E) DRAP Islamabad dated 10-08-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers	Submitted

	(real time and accelerated)	

Remarks of Evaluator [XI]:

Section	Observations	
1.3.5	• Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate dated 28-12-2023 based on inspection conducted on 09-10-2023.
1.5.2	• Clearly indicate the Strength / concentration of Active Pharmaceutical ingredient per unit in label claim along with submission of applicable fee	• The firm has submitted revised label claim without submission of applicable fee. The applied label claim is as under: Each gram contains: Terbinafine as HCl……..10mg However label claim without considering salt factor is required The firm has revised proposed brand name as Funasole 1% Solution
1.5.6	• You have applied for JP specifications while the applied product is not available in JP, clarify	• The firm submitted that Terbinafine solution monograph is available in JP. Monograph is submitted
1.6.5	• Name and address of Drug substance manufacturer shall be submitted • Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• M/s Shandong Boyuan Pharmaceutical Co., Ltd., Qianjin Street, Jibei Economic Development Zone, Jinan City, Shandong Province, China • Not submitted
3.2.S.4	• Justification shall be submitted for selecting limit of assay test as 98.0% - 102.0% in batch analysis instead of 99.0-101.0% in submitted specifications • The batch analysis of drug substance concludes that the product complies USP42 while submitted specifications is as per JP	• The firm submitted that we have adapted the method as per JP for drug substance and rug product testing while drug substance manufacturer adopted the USP method • No response submitted
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of primary / secondary reference standard including source and lot number is submitted
3.2.P.5	• In description of specification you have submitted that it is transparent solution while you have applied for topical lotion, clarification is required • You adopted analytical method of Terbinafine HCl solution of JP while applied product is Terbinafine HCl lotion, clarify	• The firm submitted that reference product Terbisil Lotion by Saffron is available in transparent solution. • The applied product is basically Topical solution and JP method is used for analysis. Word lotion has been used mistakenly instaed of solution
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of working standard including source and lot number is submitted
3.2.P.8	• Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life • The name of manufacturer mentioned on clearance certificate is M/s Tagoor Laboratories Private Limited., Sy No. 29, Tupakulagudem, Pochavaram Panchayat,	• Total batch size; 150 bottles For accelerated stability; 28 bottles For real time stability; 84 bottles Total Packs required for 24 months; 112 bottles. • Hence the batch size is sufficient for complete testing till shelf life • Firm has submitted copy of clearance certificate dated 30-07-2021 for import of 100kg of Terbinafine HCl JP (Batch#210617TA) from M/s

	Tallapudi Mandal, West Godavari-53431, Andra Pradesh India whil API manufacturer is M/s Shandong Boyuan Pharmaceutical Co., Ltd., China. Clarification is required. • The batch No# of API (TBH-II/00103/22) mentioned on clearance certificate is different than that submitted in batch analysis report of drug susbtance	Shandong Boyuan Pharmaceutical Co., Ltd., Qianjin Street, Jibei Economic Development Zone, Jinan City, Shandong Province, China in name of M/s Bio-Labs (Pvt.) Ltd attested by AD (I&E) DRAP Islamabad dated 30-07-2021. • Clearance certificate for same batch number API is submitted

Decision: Approved with following label claim:
Each gram contains:
Terbinafine HCl …….. 10mg

Registration letter will be issued after submission of:

- **Fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt factor of the drug substance) as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

229.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 28-02-2022 issued based on inspection conducted on 03-08-2021
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-12/89-Lic (Vol-IV) dated 27th September 2021 specifying Lotion (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 9093 dated 04-04-2023
	Details of fee submitted	Rs.30,000/- dated 29-03-2023 (Slip#3860075625)
	The proposed proprietary name / brand name	**Biosone Lotion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Betamethasone as Dipropionate…0.05% w/v
	Pharmaceutical form of applied drug	Lotion

	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	USP
	Proposed Pack size	60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ELEUPHRAT betamethasone 0.05% (as dipropionate) lotion bottle TGA Approved
	For generic drugs (me-too status)	Dimed Lotion 0.05% by Maxitech Pharma (Reg#83738)
	Name and address of API manufacturer.	M/s Anuh Pharma Ltd., Plot No. D-5/8 & 5/9, T.T.C. Industrial Area, M.I.D.C., Turbhe, Navi Mumbai-400703 India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Betaderm Lotion by M/s Atco Laboratories Limited.
	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, linearity and range, accuracy, precision (repeatability), system suitability.

STABILITY STUDY DATA	
Manufacturer of API	M/s Anuh Pharma Ltd., Plot No. D-5/8 & 5/9, T.T.C. Industrial Area, M.I.D.C., Turbhe, Navi Mumbai-400703 India
API Lot No.	APL/01081/C-20
Description of Pack (Container closure system)	Colorless clear solution in plastic bottle

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	BTN 22-148	BTN 22-149	BTN 22-150
Batch Size	150 Bottles	150 Bottles	150 Bottles
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	31-08-2022	31-08-2022	31-08-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Anuh Pharma Ltd., E-17/3, E-17/4 & E-18, MIDC, TARAPUR, BIOSAR-401506, Dist-Palghar Zone 3 India issued byFood and Drug Adminstration Maharashtra State India., valid till 21-06-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 30-06-2020 for import of 01kg of Betamethasone Diprpionate in name of M/s Bio-Labs (Pvt.) Ltd attested by AD (I&E) DRAP Islamabad dated 30-06-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's Response
1.3.5	• Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate dated 28-12-2023 based on inspection conducted on 09-10-2023.
1.5.2	• Clearly indicate the Strength / concentration of Active Pharmaceutical ingredient per unit in label claim along with submission of applicable fee	• The firm has submitted label claim as per reference formulation without submission of applicable fee. The applied label claim is as under: Each gram contains: Betamethasone dipropionate eq. to betamethasone……..0.5mg
1.6.5	• Name and address of Drug substance manufacturer shall be submitted • Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • Address of API manufacturer mentioned in section 3.2.S.2 is different than that	• M/s Anuh Pharma Ltd., 3-A, Shivsagar Estate, North Wing, Dr. Annie Besant Road, Mumbai-400018, India • The firm has submitted copy of cGMP certificate of M/s Anuh Pharma Ltd., A-3 Shivsagar Estate, North Wing, Dr. Annie Besant Road, Mumbai-400018, Dist-Mumbai Zone2, India issued by Food and Drugs Adminstration Maharashtra State

	given in submitted GMP certificate	India., valid till 20-04-2024. • The firm submitted that address mentiond in GMP certificate and in 3.2.S.2 both are same just differ in manner of typing.
3.2.P.5	• In description of specification you have submitted that it is transparent solution while you have applied for topical lotion, clarification is required • Justification shall be submitted for not performing the test for minimum fill in batch analysis of drug product as submitted in product specifications	• The firm submitted that innovator product DisproSone as well as reference product Effidex by Mass Pharma, is also in solution form. Basically the normal solution represents the appearance of product hence lotion dosage form can be solution. • The firm submitted that minimum fill was performed and also added in stability sheets but missed in printing error in reports. Revised reports are submitted
3.2.P.8	• Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life • Stability study data at 6th month time point is not submitted	• Total batch size; 150 bottles For accelerated stability; 28 bottles For real time stability; 84 bottles Total Packs required for 24 months; 112 bottles. • Hence the batch size is sufficient for complete testing till shelf life. • Stability study data at 6th month time point is submitted

Decision: Approved with following label claim:
Each gram contains:
Betamethasone dipropionate eq. to betamethasone……..0.5mg

- **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

230.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-12/89-Lic (Vol-IV) dated 27th September 2021 specifying Lotion (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 14716 dated 12-06-2023
	Details of fee submitted	Rs.30,000/- dated 09-06-2023

		(Slip#916181461)
	The proposed proprietary name / brand name	**C-Mycin Lotion 1% w/v**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Clindamycin as Phosphate……..…1% w/v
	Pharmaceutical form of applied drug	Lotion
	Pharmacotherapeutic Group of (API)	Lincomycin Antibiotic
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	30ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CLEOCIN T Topical Lotion 1% USFDA Approved
	For generic drugs (me-too status)	Clindapearl Lotion 1% w/v by Pearl Pharmaceuticals (Reg#109424)
	Name and address of API manufacturer.	M/s Zhejiang Hisoar Chuannan Pharmaceutical Co., Ltd., No.23, Donghai 5th Ave., Zhejiang Chemical Materials Base Linhai Zone, Linhai City, Zhejiang Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Dalacin T 1% Lotion by M/s Pfizer Pakistan Ltd.
	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, linearity and range, accuracy, precision (repeatability), system suitability.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang Hisoar Chuannan Pharmaceutical Co., Ltd., No.23, Donghai 5th Ave., Zhejiang Chemical Materials Base Linhai Zone, Linhai City, Zhejiang Province, China		
API Lot No.	P-006-CN20211221		
Description of Pack (Container closure system)	A multicolored 30ml labelled plastic bottle pack in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CLD 22-171	CLD 22-172	CLD 22-173
Batch Size	150 Bottles	150 Bottles	150 Bottles
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	04-09-2022	04-09-2022	04-09-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of written confirmation for active substance exported to EU of M/s Zhejiang Hisoar Chuannan Pharmaceutical Co., Ltd., No.23, 5th Donghai Ave., Zhejiang Chemical Materials Base Linhai Zone, Linhai City, Zhejiang Province, China valid upto 06-03-2025. The certificate states that manufacturing plant complies with the requirement of Chinese Good Manufacturing Practice. The firm has submitted copy of DML (License#ZHE20110004) of M/s Zhejiang Hisoar Chuannan Pharmaceutical Co., Ltd., No.23, 5th Donghai Avenue., Zhejiang Chemical Materials Base Linhai Zone, Zhejiang, China valid upto 23-06-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 25-07-2022 for import of 05kg of Clindamycin Phosphate USP in name of M/s Bio-Labs (Pvt.) Ltd attested by AD (I&E) DRAP Islamabad dated 25-07-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's Response

1.3.5	• Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate dated 28-12-2023 based on inspection conducted on 09-10-2023.
1.5.2	• You have claimed strength in unit of % w/v while you have applied each gram contains (w/w). Clearly indicate the Strength / concentration of Active Pharmaceutical ingredient per unit in label claim along with submission of applicable fee	• The firm has submitted the label claim for **C-Mycin Lotion 1% w/v** without submission of fee. Each ml Contains: Clindamycin Phosphate eq. to Clindamycin …….10mg
1.5.5	• Indicate correct Pharmacological class of the API (drug substance) with proper reference	• Antiinfectives for treatment of acne WHO ATC Code; D10AF01
3.2.S.4	• Justification shall be submitted for submitting specifications of drug substance as per USP specifications while applied drug product for BP specifications	• The firm submitted that specifications of drug substance adopted by following the specifications of DMF of API manufacturer i.e. USP, while for drug product we adopted BP method for testing because the dosage form lotion is not available in USP.
3.2.P.5	• In description of specification you have submitted that it is white solution while you have applied for topical lotion, clarification is required • Justification shall be submitted for selecting BP specifications for drug product for which a drug substance has been tested as per USP monograph by both drug substance manufacturer and drug product manufacturer • COA of applied product at 3rd month time accelerated stability study is submitted in batch analysis instead of COA at initial time point testing	• The term white solution basically use to describe theappearance of solution while topical lotion can be solution form because lotion are low viscosity topical preparation intended for application to the skin • The firm submitted that specifications of drug substance adopted by following the specifications of DMF of API manufacturer i.e. USP, while for drug product we adopted BP method for testing because the dosage form lotion is not available in USP. • The firm has submitted three batch analysis of the product
3.2.P.6	• Justification shall be submitted for using working standard which has been tested as per USP while the applied product claimed BP specifications	• The firm submitted that USP standard was taken along with API, while final product is not available in USP and is only available in BP.
3.2.P.8	• Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life	• Total batch size; 150 bottles For accelerated stability; 28 bottles For real time stability; 84 bottles Total Packs required for 24 months; 112 bottles. • Hence the batch size is sufficient to complete stability of product till shelf life.

Decision: Approved with following label claim:
Each ml Contains:
Clindamycin Phosphate eq. to Clindamycin ……10mg

- **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

231.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial

		Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-12/89-Lic (Vol-IV) dated 27th September 2021 specifying Lotion (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 19986 dated 11-08-2023
	Details of fee submitted	Rs.30,000/- dated 21-07-2023 (Slip#02373419703)
	The proposed proprietary name / brand name	**Flucin Lotion 0.01%**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Fluocinolone Acetonide……0.01%
	Pharmaceutical form of applied drug	Lotion
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Derma-Smoothe/FS Topical Oil, 0.01% USFDA Approved
	For generic drugs (me-too status)	Oleofin 0.01% Oil (Topical Oil) by M/s Derma Techno Pakistan (Reg#111740)
	Name and address of API manufacturer.	M/s Tianjin Tianyao Pharmaceuticals Co., Ltd., No. 19 Xin Ye 9th street, West Area of Tianjin Economic-Technological Development Area, Tianjin 300462, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 60 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Derma Smooth by M/s Valor Pharmaceutical.
	Analytical method validation/verification of product	Firm has submitted method validation studies including specificity, linearity and range, accuracy, precision (repeatability), system suitability, robustness, limit of detection and quantitation limit.

STABILITY STUDY DATA

Manufacturer of API	M/s Tianjin Tianyao Pharmaceuticals Co., Ltd., No. 19 Xin Ye 9th street, West Area of Tianjin Economic-Technological Development Area, Tianjin 300462, China		
API Lot No.	NES211113		
Description of Pack (Container closure system)	A muticolored 120ml labelled plastic bottle pack in unit carton with enclosed leaflet		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	FLU 22-134	FLU 22-135	FLU 22-136
Batch Size	150 Bottles	150 Bottles	150 Bottles
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	09-10-2022	09-10-2022	09-10-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Pranami Drugs Pvt. Ltd., Plot No. 7290 GIDC Industrial Estate, Ankleshwar, Dist. Bharuch, India.., issued by Food and Drugs Control Administration Gujarat State India valid till 19-08-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 14-05-2022 for import of 1.0kg of Fluocinolone

		Acetonide USP in name of M/s Bio-Labs (Pvt.) Ltd attested by AD (I&E) DRAP Islamabad dated 14-05-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's Response
1.3.5	• Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate dated 28-12-2023 based on inspection conducted on 09-10-2023.
1.5.2	• Standardize your label claim in line with reference formulation along with submission of applicable fee	• The firm has submitted the label claim for **Flucin Topical Oil 0.01% w/v** without submission of fee. Each ml Contains: Fluocinolon Acetonide……0.1mg However the reference product recommends label claim in w/w units.
1.5.10	• You have applied for lotion while the reference formulation is topical oil clarify?	• The firm submitted that it is topical solution in oil and applied under the lotion section. But mistakenly in cover letter it was written lotion instead of topical oil. Please consider the application as oil and grant us registration for the said for fluocinolone acetonide as topical oil.
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • GMP certificate of a different manufacturer is submitted than that the details data of which is submitted in this section and in module 3	• The firm has submitted copy of DML#JIN20150001 of M/s Tianjin Tianyao Pharmaceuticals Co., Ltd., No. 19 Xin Ye 9th street, West Area of Tianjin Economic-Technological Development Area, Tianjin 300462, China valid till 11-10-2025. • DML of relevant drug substance manufacturer is submitted
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of primary / secondary reference standard including source and lot number is submitted
3.2.S.7	• Submit stability study data of drug substance as per zone IV-A conditions till claimed shelf life	• Not submitted
3.2.P.8	• Raw data sheets of drug product at initial time point of stability study shall be submitted	• Raw data sheets of drug product at initial time point of stability study is submitted

Decision: Deferred for submission of following:

- **Standardized label claim in line with reference formulation along with submission of applicable fee**
- **Stability study data of drug substance as per zone IV-A conditions till claimed shelf life**

Case No. 06: Registration applications of New Section of Human drugs on Form 5-F (Local)

M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14-Km Adyala Road Rawalpindi.

The Central Licensing Board in its 284th meeting held on 16th December, 2021 has considered and approved the following additional section of M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14-Km Adyala Road Rawalpindi.., under Drug Manufacturing License No. 000333 (Formulation) vide approval letter No. F. 1-18/92-Lic (Vol-III) dated 13th January 2022.

S No.	Section
1	Sachet Section (General)-New
2	Oral Dry Powder Suspension (General)-New

Following applications have been submitted for registration by the firm.

232.	Name, address of Applicant / Marketing Authorization Holder	M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14Km Adyala Road Post office Dahgal Rawalpindi.
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14Km Adyala Road Post office Dahgal Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 28-12-2021 based on inspection conducted on 04-11-2021.
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-18/92-Lic (Vol-III) dated 13th January 2022 specifying Oral Dry Powder Suspension (General)-New
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	UBX-W72-2JPB dated 08-01-2024
	Details of fee submitted	Rs.30,000/- dated 19-12-2023 (Slip# 3166615335)
	The proposed proprietary name / brand name	**Erywell 200mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Erythromycin Ethylsuccinate equivalent to erythromycin……200mg
	Pharmaceutical form of applied drug	Oral Dry Suspension
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotics
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	30ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	E-MYCIN 200 erythromycin 200mg/5mL (as ethylsuccinate) powder for oral liquid bottle TGA Approved ERY-PED 200 (erythromycin ethylsuccinate) for oral suspension USFDA Approved
	For generic drugs (me-too status)	Erythrocin Granules 200mg by M/s Indus Pharma Pvt. Ltd. (Reg# 000244)

	Name and address of API manufacturer.	M/s Linaria Chemicals (Thailand) Ltd., 309, Bangpoo Industrial Estate Soi 6C, Sukhumvit Road, Moo 4, Tumbol Phraksa, Ampur Muangsamutprakan, Samutprakan, 10280, Thailand
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Erythrocin 200mg/5ml dry suspension.
	Analytical method validation/verification of product	Not submitted

STABILITY STUDY DATA

Manufacturer of API	M/s Linaria Chemicals (Thailand) Ltd., 309, Bangpoo Industrial Estate Soi 6C, Sukhumvit Road, Moo 4, Tumbol Phraksa, Ampur Muangsamutprakan, Samutprakan, 10280, Thailand		
API Lot No.	EES/M-002/22		
Description of Pack (Container closure system)	White color labeled cardboard box contains labeled amber plastic bottle		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	015NS03	015NS04	015NS05

Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation			
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of M/s Linaria Chemicals (Thailand) Ltd., 309, Bangpoo Industrial Estate Soi 6C, Sukhumvit Road, Moo 4, Tumbol Phraksa, Ampur Muangsamutprakan, Samutprakan, 10280, Thailand., issued by Food & Drugs Administration, Ministry of Public Health Thailand. The certificate states that the manufacturing site should be relied upon to reflect the compliance status until 17th June 2022. The GMP certificate is further extended to 17th June 2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 13-10-2023 for import of 10kg of Erythromycin USP in name of M/s Shaigan Pharmaceuticals. However the salt and batch No# of API is different than that given in submitted dossier (batch# EB/M-007/23).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Certificate of Compliance of HPLC software 21CFR is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Firm's response
1.3.5	• Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of letter addressed to The Additional Director (QA&LT-I) DRAP Islamabad dated 13-10-2023 for issuance of cGMP certificate.
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted	• Firm has again submitted copy of cGMP certificate of M/s Linaria Chemicals (Thailand) Ltd., 309, Bangpoo Industrial Estate Soi 6C, Sukhumvit Road, Moo 4, Tumbol Phraksa, Ampur Muangsamutprakan, Samutprakan, 10280, Thailand., issued by Food & Drugs Administration, Ministry of Public Health Thailand. The certificate states that the manufacturing site should be relied upon to reflect the compliance status until 17th June 2022. The GMP certificate is further extended to 17th June 2023.
3.2.S	• Your applied formulation contains the salt form "Erythromycin Ethylsuccinate" while you have submitted data of "Erythromycin stearate" drug substance. Clarification is	• The firm submitted that by mistake wrong module was attached. Erythromycin Ethylsuccinate is used in applied formulation

<table>
<tr><td></td><td>required for further processing of your application whether same salt form of drug substance was used in applied product or otherwise</td><td></td></tr>
<tr><td>3.2.S.4</td><td>• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required.
• Justification shall be submitted for selecting BP specifications for drug substance by drug substance manufacturer and submitting batch analysis of drug substance as per USP specifications by both drug substance manufacturer and drug product manufacturer</td><td>• Submitted
• There are no differences in the USP and BP/EP specifications of Erythromycin Ethylsuccinate for all major tests/parameters, including definition, description, solubility, assay, water content, and storage conditions. The drug substance manufacturer has conducted accelerated stability studies in accordance with BP/EP and USP 38. A copy of the studies is submitted. Additionally, the product specification for Erywell 200mg/5mL dry suspension complies with the USP.</td></tr>
<tr><td>3.2.P.2</td><td>• Compatibility studies of the Drug Substance with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.
<table>
<tr><th>Applied product</th><th>Ery-Ped 200</th></tr>
<tr><td>Erythromycin Ethyl Succinate</td><td>Erythromycin Ethyl Succinate</td></tr>
<tr><td>Sodium carboxy methyl cellulose, Sodium citrate, Quinolone yellow colour, Icing sugar, Caster sugar, Sodium Saccharin</td><td>Caramel, polysorbate, sodium citrate, sucrose, xanthan gum and artificial flavors</td></tr>
</table></td><td>• The formulation of Erywell 200mg/5mL dry suspension is similar to reference formulation (Erythromycin ethyl succinate Granules for Oral Suspension by Pinewood Laboratories Limited, Ireland.) therefore compatibility studies is not required, comparison of formulations is given in Table#1
<table>
<tr><th>Applied product</th><th>Erythromycin ethyl succinate Granules for Oral Susp.</th></tr>
<tr><td>Erythromycin Ethyl Succinate</td><td>Erythromycin Ethyl Succinate</td></tr>
<tr><td>Sodium carboxy methyl cellulose, Sodium citrate, Quinolone yellow colour, Icing sugar, Caster sugar, Sodium Saccharin</td><td>Sodium carboxy methyl cellulose, Sodium citrate, Quinolone yellow color, Banana Flavor, Sucrose (Caster sugar), Sodium Saccharin,</td></tr>
</table>
• However, the reference product has a different strength then the applied product. Primacine 250 mg/5 ml Granules for Oral Suspension Ireland approved</td></tr>
<tr><td>3.2.P.5</td><td>• Analytical method for assay test (microbial assay) for applied product is not submitted
• Analytical method verification report for assay test is not submitted</td><td>• Copy of Method of microbial assay for antibiotics is submitted
• Analytical method verification report of assay is submitted</td></tr>
<tr><td rowspan="2">3.2.P.8</td><td>• Date of initiation and implementation is mentioned as 27-12-2023 while manufacturing date of trial batches is mentioned as 12-2022 in stability summary sheets, clarify</td><td>• This is a typographical error in stability sample sheet. The date of initiation of stability was 27-12-2022 which is also mentioned on the stability summary sheets. A revised and updated copy of the stability sample sheet is submitted.</td></tr>
<tr><td>• Clarification is required since the import date of drug substance as per submitted clearance certificate (13-10-2023) is subsequent to the manufacturing date (12-2022) of trial batches (as per submitted batch</td><td>• By mistake wrong import invoice was attached that’s why there was difference in dates. New invoice is submitted.
• Firm has submitted copy of commercial invoice dated 01-09-2022 for import of 13kg of Erythromycin Ethyl succinate USP (Batch#</td></tr>
</table>

	analysis report, BMR and stability summary sheets) • The batch number of API in clearance certificate is different than that given in submitted dossier, clarify	EES/M-002/22) in name of M/s Shaigan Pharmaceuticals. However invoice is not attested by AD (I&E) DRAP.
	• Raw data sheets including calculation details for assay test is not submitted	• Raw data sheets including calculation details for assay test is submitted
	• Complete in-use stability study of batch No#015NS03 and 015NS04 shall be submitted	• In use stability summary sheets submitted
	• Stability summary sheet of batch No#015NS05 at accelerated conditions shall be submitted	• Not submitted
	• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Record of digital data logger is submitted

Decision: Deferred for submission of following:

- **Valid copy of cGMP certificate / DML of Drug Substance manufacturer issued by relevant regulatory authority of country of origin**
- **Compatibility studies of the Drug Substance with excipients as the qualitative composition of the formulation is not similar to innovator / reference product.**
- **Clearance certificate or commercial invoice attested by AD (I&E) DRAP**
- **Stability summary sheet of batch No#015NS05 at accelerated conditions**

233.	Name, address of Applicant / Marketing Authorization Holder	M/s Shaigan Pharmaceutical (Pvt.) Ltd., 14-km, Adyala Road, Post Office Dahgal, Rawalpindi
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceutical (Pvt.) Ltd., 14-km, Adyala Road, Post Office Dahgal, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 28-08-2020 based on inspection conducted on 25-09-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.1-18/92-Lic (Vol-III) dated 13-01-2022 specifying Sachet Section (General) New.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 17572 dated 13-07-2023
	Details of fee submitted	Rs.30,000/- dated 20-06-2023 (Deposit slip#982634498)
	The proposed proprietary name / brand name	**Vyber 20mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole……20mg Sodium Bicarbonate……..1680mg (as buffer)

	Pharmaceutical form of applied drug	Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1x10 sachet
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZEGERID OTC (20mg/packet ; 1.68gm/packet, 40mg/packet ; 1.68gm/packet) for Oral Suspension USFDA Approved
	For generic drugs (me-too status)	Risek Insta Sachet 20mg + 1680mg by M/s Getz Pharma (Reg# 58547)
	Name and address of API manufacturer.	**Omeprazole:** M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist.-502291 Telangana India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Omeprazole:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 05 ± 3°C for 36 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Risek Insta 20mg sachet by M/s Getz Pharmaceuticals. CDP has been performed against the same product Risek Insta 20mg sachet by M/s Getz Pharmaceuticals in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including specificity, linearity, range, Accuracy, Precision, LOD, LOQ, robustness (Omeprazole).

STABILITY STUDY DATA			
Manufacturer of API	**Omeprazole:** M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist.-502291 Telangana India		
API Lot No.	Omeprazole Powder: OME/E-347/18 (drug substance manufacturer, mfg date07-2018, exp date; 06-21) … OME-P/22006 (drug product manufacturer, mfg date01-2022, exp date; 12-26)		
Description of Pack (Container closure system)	**White color labeled cardboard box contain 1x10 labeled aluminum sachet, filled with shite, mint flavored powder for oral suspension.**		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-00.3
Batch Size	500 sachet	500 sachet	500 sachet
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	28-06-2022	28-06-2022	28-06-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Omeprazole:** Firm has submitted copy of cGMP certificate of M/s Everest Organics Limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist., 502291 Telangana India valid upto 01/08/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.5.6	• You have applied for innovator's specifications while the applied product is available in USP, clarify
1.6.5	• Name and address of API manufacturer of sodium bicarbonate shall be submitted • Valid GMP certificate / DML of Drug Substance manufacturer for omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin is required
3.2.S	• Submit complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance omeprazole by Drug substance manufacturer and drug product manufacturer is required. • Provide COA of relevant batch of Drug Substance omeprazole from Drug substance manufacturer used during product development and stability studies.
3.2.S.5	• COA of primary / secondary reference standard for omeprazole including source and lot number shall be provided.
3.2.P.1	• Justification is required as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation
3.2.P.5	• Justification shall be submitted for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document • Justification shall be submitted for selecting different limit of pH test (6.5-8.0)in finished product specifications than USP monograph (7.5-8.5) • Justification shall be submitted for using different chromatographic conditions (wavelength (280nm), flow rate (0.8ml/min), injection volume (20ul), column specifications (L7, 4.6mmx150umx5um) for assay test of omeprazole than USP monograph
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Detailed raw data sheet for stability testing is not submitted • UV absorbance value or spectra for dissolution testing is not submitted in stability study • Submit documents for the procurement of API with approval from DRAP (in case of import).

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

234.	Name, address of Applicant / Marketing Authorization Holder	M/s Shaigan Pharmaceutical (Pvt.) Ltd., 14-km, Adyala Road, Post Office Dahgal, Rawalpindi
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceutical (Pvt.) Ltd., 14-km, Adyala Road, Post Office Dahgal, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 28-08-2020 based on inspection conducted on 25-09-2019

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.1-18/92-Lic (Vol-III) dated 13-01-2022 specifying Sachet Section (General) New.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 17573 dated 13-07-2023
	Details of fee submitted	Rs.30,000/- dated 20-06-2023 (Deposit slip#307907903)
	The proposed proprietary name / brand name	**Vyber 40mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole……40mg Sodium Bicarbonate……..1680mg (as buffer)
	Pharmaceutical form of applied drug	Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1x10 sachet
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZEGERID OTC (20mg/packet ; 1.68gm/packet, 40mg/packet ; 1.68gm/packet) for Oral Suspension USFDA Approved
	For generic drugs (me-too status)	Risek Insta Sachet 40mg + 1680mg by M/s Getz Pharma (Reg# 58548)
	Name and address of API manufacturer.	**Omeprazole:** M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist.-502291 Telangana India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	**Omeprazole:**

	(Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 05 ± 3°C for 36 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Risek Insta 40mg sachet by M/s Getz Pharmaceuticals. CDP has been performed against the same product Risek Insta 40mg sachet by M/s Getz Pharmaceuticals in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including specificity, linearity, range, Accuracy, Precision, LOD, LOQ, robustness (Omeprazole).

STABILITY STUDY DATA			
Manufacturer of API	**Omeprazole:** M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist.-502291 Telangana India		
API Lot No.	Omeprazole Powder: OME/E-347/18 (drug substance manufacturer, mfg date07-2018, exp date; 06-21) … OME-P/22006 (drug product manufacturer, mfg date01-2022, exp date; 12-26)		
Description of Pack (Container closure system)	**White color labeled cardboard box contain 1x10 labeled aluminum sachet, filled with shite, mint flavored powder for oral suspension.**		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-00.3
Batch Size	500 sachet	500 sachet	500 sachet
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	26-07-2022	26-07-2022	26-07-2022
No. of Batches	03		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Omeprazole:** Firm has submitted copy of cGMP certificate of M/s Everest Organics Limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist., 502291 Telangana India valid upto 01/08/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.6.5	• Name and address of API manufacturer of sodium bicarbonate shall be submitted • Valid GMP certificate / DML of Drug Substance manufacturer for omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin is required
1.5.6	• You have applied for innovator's specifications while the applied product is available in USP, clarify
3.2.S	• Submit complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance omeprazole by Drug substance manufacturer and drug product manufacturer is required. • Provide COA of relevant batch of Drug Substance omeprazole from Drug substance manufacturer used during product development and stability studies.
3.2.S.5	• COA of primary / secondary reference standard for omeprazole including source and lot number shall be provided.
3.2.P.1	• Justification is required as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation
3.2.P.5	• Justification shall be submitted for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document • Justification shall be submitted for selecting different limit of pH test (6.5-8.0)in finished product specifications than USP monograph (7.5-8.5) • Justification shall be submitted for using different chromatographic conditions (wavelength (280nm), flow rate (0.8ml/min), injection volume (20ul), column specifications (L7, 4.6mmx150umx5um) for assay test of omeprazole than USP monograph
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Detailed raw data sheet for stability testing is not submitted • Chromatograms for stability testing at 6th month time point is not submitted • UV absorbance value or spectra for dissolution testing is not submitted in stability study • Submit documents for the procurement of API with approval from DRAP (in case of import).

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

Case No. 07: Registration applications of New Section of Human drugs on Form 5-F (Local)

M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No.E-127-129, North Western Industrial Zone, Port Qasim Authority Karachi

The Central Licensing Board in its 280th meeting held on 26th – 27th April, 2021 has considered and approved the following additional section of **M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No.E-127-129, North Western Industrial Zone, Port Qasim Authority Karachi**.., under Drug Manufacturing License No. 000755 (Formulation) vide approval letter No. F. 2-5/2009-Lic (Vol-I) dated 18th May 2021.

S No.	Section
1	Soft Gelatin Capsule (General)-New

Following applications have been submitted for registration by the firm.

235.	Name, address of Applicant / Marketing Authorization Holder	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No.E-127, E-128 & E-129, North Western Industrial Zone, Port Qasim Authority Karachi
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No.E-127, E-128 & E-129, North Western Industrial Zone, Port Qasim Authority Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 26-06-2023 based on inspection conducted on 03-01-2023.
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 2-5/2009-Lic (Vol-I) dated 18th May 2021 for grant of additional section specifying Soft Gelatin Capsule (General)-New.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID: 3DH-4X9-RRXT dated 06-02-2024
	Details of fee submitted	PKR 75,000 /- Dated 14-11-2023 **(Deposit slip# 4619862787)**
	The proposed proprietary name / brand name	**Colicalm 125mg Soft Gelatin Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains: Simethicone.....125mg
	Pharmaceutical form of applied drug	Soft Gelatin Capsule
	Pharmacotherapeutic Group of (API)	Anti-flatulence Agent
	Reference to Finished product specifications	Innovators Specification
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SIMETHICONE 125mg Softgel Capsules Health Canada Approved

	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Sudeep Pharmaceuticals Private Limited., 129/1/A, 129/12, 13, 14, 15, G.I.D.C Estate, Nandesari- 391 340. Vadodara, Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Gas-X Extra strength soft gel liquid filled capsule by M/s GlaxoSmithKline.
	Analytical method validation/verification of product	Firm has submitted method validation studies including accuracy, precision (repeatability, intermediate), linearity, range, robustness, specificity, detection limit, quantitation limit.

STABILITY STUDY DATA	
Manufacturer of API	M/s Sudeep Pharmaceuticals Private Limited., 129/1/A, 129/12, 13, 14, 15, G.I.D.C Estate, Nandesari- 391 340. Vadodara, Gujarat, India
API Lot No.	17/G/SI/001
Description of Pack (Container closure system)	ALU/PVC Blister Packs along with the Package Inserts are packed in a carton box.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH

	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1000 Capsule	1000 Capsule	1000 Capsule
Manufacturing Date	02-2018	02-2018	02-2018
Date of Initiation	02-2018	02-2018	02-2018
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection for authenticity of stability data of their product conducted by the panel on the basis of which Registration Board in 290th meeting dated 3rd - 4th July, 2019 decided to approve registration of Rofair 500mcg tablet. Inspection date: 25th June, 2019 (Forenoon) The report shows that: • The HPLC software is 21 CFR compliant. • Audit Trail on the testing reports are available. Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Sudeep Pharma Private Limited., 129/1/A, 129/12 G.I.D.C Estate, AT & POST Nandesari- Dist-Vadodara, India issued by Food & Drugs Control Gandhinagar, Gujarat State India valid upto 31-05-2018
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice for import of Simethicon USP 1.505kg in name of M/s Kaizan Pharmaceuticals attested by AD (I&E) DRAP Karachi dated 14-11-2017.
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets, and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable as HPLC method was not used for testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.5.6	• You have applied for innovator's specifications while the applied product is available in USP, clarify
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required

3.2.S.4	• Justification shall be submitted for not including the test for Content of Silicon Dioxide in drug substance specification by drug product manufacturer as per USP monograph • The submitted assay method for drug substance by drug product manufacturer is different than USP monograph and drug substance manufacturer (IR spectrophotometric method), clarify • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance as per USP monograph shall be submitted. • The manufacturing and expiry date of drug substance as per submitted COA of drug substance manufacturer is July 2017 and June 2019 while manufacturing and expiry date of drug substance as per submitted COA of drug product manufacturer is 11-2021 and 11-2023. Clarification is required • Justification shall be submitted for not performing the test for Content of Silicon Dioxide in batch analysis of drug substance by drug product manufacturer
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.2	• Justification shall be submitted for not performing the test for uniformity of dosage unit and disintegration test in pharmaceutical equivalence studies as USP monograph • Details of reference product including batch number, manufacturing date, expiry date and country of MAH shall be provided • Drug excipient compatibility study shall be submitted as the qualitative composition of applied product is not similar to reference product
3.2.P.5	• The submitted assay method for applied product is different than USP monograph, clarify • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug product as per USP monograph shall be submitted.
3.2.P.8	• Justify the production of trial batches (02-2018) before issuance of section approval letter (18-05-2021) • Justify the assay testing of applied product by evaporation method instead of IR spectrophotometric method as per USP monograph
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings	

Case No. 08: Registration applications of New Section of Human drugs on Form 5-F (Local)

M/s Pearl Pharmaceuticals., Plot No. 204, Street 1, I-10/3 Industrial Area, Islamabad

The Central Licensing Board in its 289th meeting held on 3rd January, 2023 has considered and approved the Renewal of Drug Manufacturing License / Regularization / New Sections of **M/s Pearl Pharmaceuticals., Plot No. 204, Street 1, I-10/3 Industrial Area, Islamabad**., under Drug Manufacturing License No. 000479 (Formulation) vide approval letter No. F. 1-18/90-Lic (Vol-III) dated 21st February 2023.

S No.	Section
1	Ampoule (General)-New
2	Infusion SVP (General)-New
3	Dry powder for Injection (General)-New

Following applications have been submitted for registration by the firm.

236.	Name, address of Applicant / Marketing Authorization Holder	M/s Pearl Pharmaceuticals., Plot #204, Street# 01, I-10/3 Industrial Area, Islamabad
	Name, address of Manufacturing site.	M/s Pearl Pharmaceuticals., Plot #204, Street# 01, I-10/3 Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 28-02-2023 based on inspection conducted on 03-11-2022.
	Evidence of approval of manufacturing facility	**New Section** Firm has submitted copy of letter No. F. 1-18/90-Lic (Vol-III) dated 21st February 2023 for Renewal of Drug Manufacturing License / Regularization / New Sections specifying Ampoule (General)-New section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID; 9NE-PPY-TDQ4 dated 23-02-2024
	Details of fee submitted	PKR 30,000 /- Dated 09-02-2024 **(Deposit slip# 19834350466)**
	The proposed proprietary name / brand name	**D-Pearl 5mg/ml Ampoule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	1ml ampoule contains; Cholecalciferol……5mg (200,000I.U)
	Pharmaceutical form of applied drug	Ampoule
	Pharmacotherapeutic Group of (API)	Vitamin D analog
	Reference to Finished product specifications	Innovators Specification
	Proposed Pack size	1x1ml ampoule
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	VITAMIN D3 GOOD 200,000 IU/1 ml, IM injection solution in ampoule ANSM (France) Approved
	For generic drugs (me-too status)	Indrop-D Injection by M/s Neutro Pharma (Reg#023170)
	Name and address of API manufacturer.	M/s Sichuan Province Yuxin Pharmaceutical Co., Ltd., No.51 west section of Changjiang Road, Economic Development (south district), Shifang City, Sichuan Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure

		system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 06 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Indrop-D Injection by M/s Neutro Pharma.
	Analytical method validation/verification of product	Firm has submitted method validation studies including specificity, linearity, range, accuracy, precision (repeatability, intermediate), robustness, LOD, LOQ.

STABILITY STUDY DATA

Manufacturer of API	M/s Sichuan Province Yuxin Pharmaceutical Co., Ltd., No.51 west section of Changjiang Road, Economic Development (south district), Shifang City, Sichuan Province, China.		
API Lot No.	221223		
Description of Pack (Container closure system)	Clear and colorless solution filled in clear transparent glass ampoule (USP Type I) free from visible foreign particles fitted in plastic Ampoule protector and further packed in Unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	D-T2	D-T3	D-T4
Batch Size	1000 Ampoule	1000 Ampoule	1000 Ampoule
Manufacturing Date	08-2023	08-2023	08-2023
Date of Initiation	28-08-2023	28-08-2023	28-08-2023
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of License (DML#20160429) of M/s Sichuan Province Yuxin Pharmaceutical Co., Ltd., No.51 west section of Changjiang Road, Economic Development (south district), Shifang City, Sichuan Province, China.

		issued by Sichuan Food & Drugs Administration valid upto 18-10-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted letter for borrowing of raw material (12gm) for stability batches from Bio-Lab Pharmaceuticals, along with copy of form 5 and clearance certificate.
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. • Complete Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.S.7	• Submit stability study data of drug substance at real time conditions as per zone IV-A conditions till claimed shelf life
3.2.P.2	• Details of reference product including, manufacturing date and expiry date shall be provided
3.2.P.5	• The analytical method for sterility test is not submitted for the applied product • Numerical value of results shall be reported in the test for standard volume instead of writing complies in batch analysis
3.2.P.8	• Justify the quantity of API required for manufacturing of three batches of 1000 ampoules • Stability study data at 6th month time point for applied product is not submitted • Chromatograms of batch# D-T2 at 3rd month time point of stability testing (both accelerated and real time conditions) is not submitted

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

Agenda of Evaluator PEC-XIII

Case No. 01. Registration applications of locally manufactured Human cases of new License/new sections on form 5F.

CLB in its 284th meeting held on 16th December 2021 has considered and approved the grant of following four (04) additional section to M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura;

- Capsule (Penicillin). – New.
- Oral Dry Powder Suspension (Penicillin). – New.
- Dry Powder Injectable (Penicillin). – New.
- Dry Powder Injectable (Carbapenem). – New.

Following applications of M/s Fynk Pharma are placed before the Board for consideration.

237.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fynk Pharmaceuticals, 19 km, G.T. Road, Kalashah Kaku, Lahore.**

	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals, 19 km, G.T. Road, Kalashah Kaku, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection 14/11/2022.
	Evidence of approval of manufacturing facility	Dry powder injectable (Penicillin). – New section approved vide letter No. F. 1-63/84-Lic (Vol III) dated 27-12-2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 15248 dated 16-06-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 116976395 Dated 14-03-2023.
	The proposed proprietary name / brand name	**Ampiwell 500mg for injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ampicillin as Sodium …… 500mg.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin's.
	Pharmaceutical form of applied drug	Powder for injection.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	1's (one vial packed with 5ml of WFI).
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Penbritin-S Eq. 500 base/vial USFDA approved. **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	Zampicillin Injection 500mg, Zafa Pharmaceutical Laboratories, Reg. No. 037825.
	Name and address of API manufacturer.	Vartika Chemicals & Pharmaceuticals Pvt. Ltd., G1-567, RIICO Industrial Area, Khushkhera, Bhiwadi – 301019 Dist. Bhiwadi (Rajasthan), India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of

		manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (ASS-0422043, mfg. date 04-2022) and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. ASS-0117001, ASS-0117002 & ASS-0117003.
	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 drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Ampicillin sodium 500mg for injection, manufactured by Chongquing medicine and health products, batch No. 211028, mfg. date 10-2021 by performing quality test pH, Average weight, water content, assay and sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Vartika Chemicals & Pharmaceuticals Pvt. Ltd., G1-567, RIICO Industrial Area, Khushkhera, Bhiwadi – 301019 Dist. Bhiwadi (Rajasthan), India.		
API Lot No.	ASS-0422043.		
Description of Pack (Container closure system)	Glass vial type II with rubber stopper and aluminium flip of seal.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period.	Real time: 6 months Accelerated: 6 months		
Frequency.	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size .	400 Vials	400 Vials	400 Vials
Manufacturing Date.	07-2022	07-2022	07-2022
Date of Initiation.	30-07-2022	30-07-2022	30-07-2022
No. of Batches.	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. DC/A-I/2020/1517 dated 09-09-2020 issued by Drug Control Organization, Rajasthan, Jaipur. Valid till 11-04-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate No. 6893/2022DRAP dated 07-06-2022 mentioning 2kg of Ampicillin Sodium sterile (BP) with batch No. ASS-0422043, mfg. date of 30-04-2022 from M/s Vartika Chemicals & Pharmaceuticals Pvt. Ltd., India attested by Assistant Director, I&E, DRAP, Lahore dated 07-06-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of drug substance manufacturer issued by the concerned/relevant regulatory authority shall be submitted.	Copy of GMP certificate (DC/Mfg-25/E-01761/GMP/2023/4069 dated 06-10-2023) of drug substance manufacturers issue by Food Safety and Drugs Control Commissionerate valid for three years is submitted.
2.	3.2.P.2.2	• Justification shall be submitted for submitting same results as that of the 1gm strength of the same formulation. • Justification shall be submitted for not performing pharmaceutical equivalence against the innovator product. • Justification for not performing different tests like identification, BET, particulate matter test etc. in pharmaceutical equivalence studies.	Firm has submitted that while preparing the pharmaceutical equivalence report, results of 1gram were mentioned mistakenly. They also submitted new results for the applied strengths. Innovator pack is not available in market, so we used competitor pack pharmaceutical equivalence as per guidance documents. Tests like Identification, BET & Particulate matter were performed on products; the same had also been performed on compotator packs, Updated pharmaceutical equivalence report has mentioned all these tests.
3.	3.2.P.5.2	Assay calculation formula in the analytical procedures shall be elaborated. As only formula is given while there is no elaboration of the formula.	Submitted.
4.	3.2.P.8	• Raw data sheets for calculation of assay of ampicillin at each time interval with calculation formula shall be submitted.	Submitted.

		• Justify the submitted chromatograms with respect to BP monograph wherein it is mentioned that "the assay is not valid unless, in the chromatograms obtained with solution (3), the resolution peaks between the peaks due to ampicillin and Cefradine is at least 3.0. if necessary, adjust the composition of the mobile phase to achieve the desired resolution." • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Firm has submitted that system suitability injection was run separately by preparing the solution with working standard of Ampicillin and Cefradine, it is not used for the calculation of Assay results. They also submitted separate chromatograms. Application approved in different meeting (323, 324) on Form 5F.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

238.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fynk Pharmaceuticals, 19 km, G.T. Road, Kalashah Kaku, Lahore.**
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals, 19 km, G.T. Road, Kalashah Kaku, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection 14/11/2022.
	Evidence of approval of manufacturing facility	Capsule (Penicillin) – New section approved vide letter No. F. 1-63/84-Lic (Vol III) dated 27-12-2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 16406 dated 27-06-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 96593694 Dated 17-05-2023.
	The proposed proprietary name / brand name	**Ampiwell 500mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Ampicillin as trihydrate …… 500mg
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Pharmaceutical form of applied drug	Oral capsule.
	Reference to Finished product specifications	BP specifications.

	Proposed Pack size	100's capsules.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Ampicillin Capsules BP 500 mg, Crescent Pharma Limited, MHRA approved.
	For generic drugs (me-too status)	Penbritin 500mg Capsule, GSK Pakistan, Reg. No. 000189.
	Name and address of API manufacturer.	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore. Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 00003/093/2021, mfg. date 11-2021) and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data sheets of three batches for the drug substance. Real time stability conducted at 30°C ± 2°C / 65% ± 5% RH for 60months. Accelerated stability conducted at 40°C ± 2°C / 75% ± 5% RH for 06 months. B. No. (00003/001/2015, 00003/002/2015 & 00003/003/2015)
	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 drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Penbritin 500mg capsule, B. No. UH2X, mfg. date 06-2021manufactured by GSK, Pakistan by performing quality tests od identification, average filled weight, dissolution and assay. Firm has also submitted comparative dissolution of their applied formulation with Penbritin 500mg

		capsule B. No. UH2X, mfg. date 06-2021manufactured by GSK, Pakistan in three different mediums of pH 1.2, 4.5 & 6.8. values of the F_2 are in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.		
API Lot No.	00003/093/2021.		
Description of Pack (Container closure system)	Almost white granular powder filled in purple and white capsule packed in printed Alu - Alu blister of 20 capsules further packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A	B	C
Batch Size	2000 Capsules	2000 Capsules	2000 Capsules
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	08-02-2022	08-02-2022	08-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Proforma invoice No. PL/P-INV/HO/866 dated 03-01-2022 wherein they have purchased 1kg of Ampicillin trihydrate from M/s Pharmagen Limited. However, the invoice has not mentioned any batch number and manufacturing date of the drug substance.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	

2.	2.3	Table for literature references with correct information with applicable fee shall be submitted.	
3.	3.2.S.6	Details/COA of the working standard used in the trial batches shall be submitted.	
4.	3.2.S.7	Justification shall be submitted for not performing all the test in stability data sheets as required by monograph.	
5.	3.2.P.2.2	Justification shall be submitted for providing exact same results for dissolution and assay test in pharmaceutical equivalence studies of two different strengths of Ampicillin 250mg and 500mg.	
6.	3.2.P.5.1	Justification shall be submitted for adopting all the specifications for the finished product from BP while only dissolution test is adopted from USP.	
7.	3.2.P.5.3	• Justification shall be submitted for providing analytical method verification studies of 250mg capsule for 500mg capsule. • Justification shall be submitted regarding the submitted chromatograms as they have mentioned 200mg, 250mg and 300mg ampicillin capsules.	
8.	3.2.P.8	• Proforma invoice provided by the firm has not mentioned any batch number and mfg. date. Clarify. • Justification shall be submitted regarding the submitted quantity of 1kg with respect to manufactured batches of 2000 capsule each of three batches.	

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

239.	Name, address of Applicant / Marketing Authorization Holder	**M/s Fynk Pharmaceuticals, 19 km, G.T. Road, Kalashah Kaku, Lahore.**
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals, 19 km, G.T. Road, Kalashah Kaku, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection 14/11/2022.
	Evidence of section approval	Dry Powder Injectable (Penicillin) section - New approved vide letter No. F. 1-63/84-Lic (Vol-III) dated 27-12-2021.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26047 dated 27-10-2023.
	Details of fee submitted	PKR 30,000/-, vide slip No. 199540998741, Dated 25/09/2023.
	The proposed proprietary name / brand name	**FAXCIL 500 mg for injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Amoxicillin as Sodium ……..……. 500mg.
	Pharmaceutical form of applied drug	Powder for injection.

	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Reference to Finished product specifications	BP Specifications.
	Proposed Pack size	1's (one vial packed with 10ml of WFI).
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Amoxicillin 500mg Powder for Solution for Injection, MHRA approved.
	For generic drugs (me-too status)	Neomentin 600mg Injection, Libra (Pvt.) Ltd, Reg. No. 027634.
	Name and address of API manufacturer.	Vartika Chemicals & Pharmaceuticals Pvt. Ltd., G1-567, RIICO Industrial Area, Khushkhera, Bhiwadi – 301019 Dist. Bhiwadi (Rajasthan), India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of drug substance regarding its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. AMX-0422060, mfg. date 04-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (AMX-0117001, AMX-0117002 & AMX-0117003)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description and composition, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the competitor product i.e. Penbro 500mg for injection, B. No. PB230501, mfg. date of 08-2022 manufactured by M/s PDH Laboratories by performing quality tests weight content, pH, water content, Assay, sterility, BET, particulate matters).
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Vartika Chemicals & Pharmaceuticals Pvt. Ltd., G1-567, RIICO Industrial Area, Khushkhera, Bhiwadi – 301019 Dist. Bhiwadi (Rajasthan), India.		
API Lot No.	AMX-0422060.		
Description of Pack (Container closure system)	Type II glass vial with rubber stopper and aluminum flip of seal.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	300 vials	300 vials	300 vials
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	16-11-2022	16-11-2022	16-11-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. DC/A-I/2020/1517 dated 09-09-2020 issued by Drug Control Organization, Rajasthan, Jaipur. Valid till 11-04-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate No. 6893/2022DRAP (E-1393520227361) dated 07-06-2022 mentioning 1kg of Amoxicillin Sodium sterile (BP) with batch No. AMX-422060, mfg. date of 30-04-2022 from M/s Vartika Chemicals & Pharmaceuticals Pvt. Ltd., India attested by Assistant Director, I&E, DRAP, Lahore dated 07-06-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of the GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. DC/Mfg-25/E-01761/GMP/2023/4069 dated 06-10-2023 issued by Food Safety and drugs control Commissionerate government of Rajasthan valid for three years.

2.	3.2.S.4.2	Analytical procedures for the drug substance from both drug substance and drug product manufacturer are different from BP monograph. Clarification shall be submitted.	Firm has submitted that analytical method used for drug substance is in accordance with BP monograph of drug product. Since we are importing ready to fill powder of Amoxicillin sodium and the same is filled in vials without any processing, so we adopted BP method of drug product for the testing of drug substance.
3.	3.2..4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.5	Details and COA of the working standard used in the development of trial batches shall be submitted.	Firm has submitted copy of working standard used in the development of trial batches
5.	3.2.P.2.2	Justification shall be submitted for not performing pharmaceutical equivalence against the innovator product.	Firm has submitted that since innovator product is not available in market, so we conducted pharmaceutical equivalence study against comparator product.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

CLB in its 276th meeting held on 03rd September, 2020 has considered and approved the grant of one (04) additional sections to M/s Quaper (Pvt.) Ltd., 26-A, Small Industrial Estate Lahore Road Sargodha;

- Tablet (General) Section (Revised).
- Capsule (General) Section (New).
- R&D Laboratory (New)
- Sachet (general). (New)

Firm has also submitted letter No. 1-37/2003-Lic (Vol-I) dated 19-03-2021 wherein it is stated that name of the section "Tablet (General) Section (Revised)" is corrected to Tablet (General) Section (New).

Following applications of M/s Quaper Pharma are placed before the Board for consideration.

240.	Name, address of Applicant / Marketing Authorization Holder	**M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 124/2022-DRAP (AD-199037819226) dated 22-08-2022 issued on the basis of inspection conducted on 16-08-2022 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-37/2003-Lic (Vol-I) dated 29/09/2020 specifying Capsule (General) section (New).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 24303, dated 04/10/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 28499350 dated: 25/09/2023.
	The proposed proprietary name / brand name	**Flucol 150mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Fluconazole ……. …… 150mg
	Pharmacotherapeutic Group of (API)	Antifungal. (J02AC01)
	Pharmaceutical form of applied drug	Oral capsule.
	Reference to Finished product specifications	BP specification.
	Proposed Pack size	As per SRO/DPC.
	Proposed unit price	As per SRO/DPC.
	The status in reference regulatory authorities	Fluconazole 150 mg Capsules, MHRA approved.
	For generic drugs (me-too status)	Flucoz 150mg Capsule, Albro Pharmaceutical, Reg. No. 067807.
	Name and address of API manufacturer.	M/s Hema Pharmaceuticals (Pvt.) Ltd., Plot No. 6201/A&B, GIDC Estate, Opposite EWAC Alloy Ltd., Ankleshwar, Gujrat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. HBPL/FCZ/20-21/003, Mfg. date 08-06-2020) (21FC0001, mfg. date 01-2021 from DS manufacturer) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5% RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (12PDFC001, 12PDFC002 & 12PDFC003)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative	Pharmaceutical Equivalence is established against the

	dissolution profile	innovator product i.e. Diflucan capsule, Batch No. 1890017, mfg. date 08-2020 by performing quality tests Identification, weight variation, disintegration time, Dissolution & Assay. Results of both the test product and innovator product are comparable. Comparative Dissolution is also performed against the same product i.e. Diflucan capsule in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). Values of F_2 are in acceptable ranges.
	Analytical method validation/verification of product	Method verification studies are submitted including System suitability, specificity, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Hema Pharmaceuticals (Pvt.) Ltd., Plot No. 6201/A&B, GIDC Estate, Opposite EWAC Alloy Ltd., Ankleshwar, Gujrat, India.		
API Lot No.	21FC0001.		
Description of Pack (Container closure system)	White to off white powder filled in Blue/blue hard gelatin capsule shell.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 Capsules	1000 Capsules	1000 Capsules
Manufacturing Date	08/2022	08/2022	08/2022
Date of Initiation	18/08/2022	19/08/2022	20/08/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate for M/s Morepen laboratories..
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. EXP 079 dated 03-02-2021 mentioning 50kg of Fluconazole USP, B. No. 21FC0001, mfg. date 01-2021 in the name of M/s Wimits pharmaceutical Lahore. Invoice is attested by Assistant Director, DRAP, Lahore dated 08-03-2021. Firm has also submitted loan letter of 1.5kg of Fluconazole from M/s Wimits Pharmaceuticals, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.

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

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML no. 000609 date of renewal w.e.f. 21-03-2022.
2.	1.5.6	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. S-GMP & GLP/22073413 issued by Food & Drug Control Administration Gujrat state India to M/s Hema Pharmaceuticals valid from 04-07-2022 to 03-07-2024.
3.	2.3.R	Copies of executed BMR's shall be submitted.	Submitted.
4.	3.2.S.4.2	Analytical procedures of the drug substance submitted by both the drug substance manufacturer and drug product manufacturer has assay test on potentiometric method while the official monograph has assay test on HPLC method. Specifications are also as per USP monograph. Justification shall be submitted.	Firm has submitted that drug substance was imported and tested in 2022. The specifications followed by drug substance manufacturer as well as Quaper pharma was USP. The USP version in 2022 contains the assay method based on potentiometric titration, so the same method was followed.
5.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.4	• Justification shall be submitted for overwriting the COA of the drug substance from drug substance manufacturer. • COA of the drug substance from both the drug substance manufacturer and drug product manufacturer with same batch number shall be submitted. • Original COA of the drug substance from drug substance manufacturer shall be submitted. • COA of the drug substance from both the drug substance manufacturer and drug product manufacturer has mentioned USP specifications while the analytical method has assay method other than USP monograph. Clarification shall be submitted.	Firm has submitted new COA for the drug substance from drug substance manufacturer. *However, in the initially submitted COA results were over written.* Submitted. Submitted. drug substance was imported and tested in 2022. The specifications followed by drug substance manufacturer as well as Quaper pharma was USP. The USP version in 2022 contains the assay method based on potentiometric titration, so the same method was followed.
7.	3.2.S.5	Details/COA of the reference standard/working standard used in the analysis shall be submitted.	Firm has submitted copy of COA of working standard with batch No. 19WSFC001.
8.	3.2.P.2.2	• Details of the product i.e. name of manufacturer, batch number,	Firm has submitted details of the innovator product as follows;

		manufacturing date and expiry date etc. against which PE & CDP are performed shall be submitted with clear and visible pictorial evidence.	Diflucan 150mg capsule, B. No. 4C0328, mfg. date 01-2022, Exp. date 01-2025 manufactured by Pfizer Pakistan.
9.	3.2.P.8	• Stability data sheets as per decision of Registration Board with inclusion of API lot number shall be submitted. • Provide submission of the document for loan of API in DRAP within 30 days as per Notification No. 14-1/2022-PEC dated 16-01-2023. • Justification shall be submitted for using 100% potency of the drug substance in the submitted raw data sheets with respect to the assay of drug substance in 3.2.S.4.4. • Submitted chromatograms does not reflect any wave length. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Firm has submitted revised stability data sheets with inclusion of API lot No. 21FC0001. *Firm has submitted a document with subject of "Borrowing of API." Wherein they have borrowed API from M/s Wimits Pharma and the same document is submitted in DRAP dated 14-02-2023 as per directions of Notification No. 14-1/2022-PEC dated 16-01-2023 within 30 days.* Firm has submitted that the potency of the API varies from lot to lot, so the quantity in the formulation also varies. The standard master formulation is given in the P part of the dossier using 100% potency. However, note is also added that the final quantity of the API is to be calculated based on the released potency of the drug substance. The quantity used in the trial batches was adjusted with respect to potency. Firm has submitted that the chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that wavelength which was set in the method. The wavelength is mentioned in the standard analytical procedure of the product. Firm has submitted that the chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is not 21CFR compliant. Firm has submitted that no previous approval is available.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
241.	Name, address of Applicant / Marketing Authorization Holder	**M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 124/2022-DRAP (AD-199037819226) dated 22-08-2022 issued on the basis of inspection conducted on 16-08-2022 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-37/2003-Lic (Vol-I) dated 19/03/2021 specifying Tablet (General) section (New).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	VSV-G4V-APQB dated 16-01-2024.
	Details of fee submitted	PKR 30,000/- vide slip No. 9512542272 dated: 03/11/2023.
	The proposed proprietary name / brand name	**Onolid 400mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linezolid ……. …… 400mg
	Pharmacotherapeutic Group of (API)	Other antibacterial (J01XX)
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO/DPC.
	Proposed unit price	As per SRO/DPC.
	The status in reference regulatory authorities	ZYVOX® (linezolid) 400mg tablets, USFDA approved. ****Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons****
	For generic drugs (me-too status)	Lyzon 400mg Tablet, Getz Pharma, Reg. No. 055434.
	Name and address of API manufacturer.	M/s Optrix Laboratories Private Limited, Survey No. 145/A, 145/AA & 147, Ramalingampally (V), Bommala ramaram (M), Yadadri – Bhuvanagiri (Dist)-508 126, Telangana, India. Firm has submitted copy of GMP certificate No. 5207/TS/2022 dated 14-09-2022 issued by Drugs Control Administration Government of Telangana valid till 14-12-2023.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature,

		structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. OT-LID/12/20/048, Mfg. date 12-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5% RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (OT-LID-S2-002/16, OT-LID-S2-003/16 & OT-LID-S2-004/16)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the comparator product i.e. Zoldap 400mg tablets, manufactured by Getz pharma by performing quality tests Identification, weight variation, disintegration time, Uniformity of dosage units, Dissolution & Assay. Results of both the test product and innovator product are comparable. Comparative Dissolution is also performed against the same product i.e. Zoldap 400mg tablets, manufactured by Getz pharma in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). Values of F2 are in acceptable ranges.
	Analytical method validation/verification of product	Method verification studies are submitted including System suitability, specificity, accuracy, precision.

STABILITY STUDY DATA	
Manufacturer of API	M/s Optrix Laboratories Private Limited, Survey No. 145/A, 145/AA & 147, Ramalingampally (V), Bommala ramaram (M), Yadadri – Bhuvanagiri (Dist)-508 126, Telangana, India.
API Lot No.	OT-LID/12/20/048.
Description of Pack	Alu/Alu Blister 0f 2 x 7's tablets with leaflet.

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	
Batch Size	5000 Tablets	5000 Tablets	
Manufacturing Date	08/2022	08/2022	
Date of Initiation	08/2022	08/2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 5207/TS/2022 dated 14-09-2022 issued by Drugs Control Administration Government of Telangana valid till 14-12-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	
2.	1.5.6	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
3.	2.3	Copies of executed BMR's shall be submitted.	
4.	3.2.S.4.1	Specifications of the drug substance provided by the drug product manufacturer are different from that provided by the drug substance manufacturer. Justification shall be submitted.	
5.	3.2.S.4.2	Analytical procedures of the drug substance submitted by the drug substance manufacturer are different from USP monograph. Justification shall be submitted.	
6.	3.2.S.4.4	COA of the drug substance from drug substance manufacturer has mentioned in-house specifications while that from drug product manufacturer has mentioned USP specifications. Clarification shall be submitted.	

7.	3.2.S.4.5	Justification of specification is for some other drugs. Clarification shall be submitted.	
8.	3.2.S.7	• Justification shall be submitted for over writing the real time stability conditions in the submitted stability data sheets for the drug substance. • Real time stability data of the three batches for drug substance as per zone Iva shall be submitted.	
9.	3.2.P.2.2	• Justification shall be submitted for not performing PE & CDP against the innovator product. • Details of the product i.e. name of manufacturer, batch number, manufacturing date and expiry date etc. against which PE & CDP are performed shall be submitted with clear and visible pictorial evidence.	
10.	3.2.P.8	• Justification shall be submitted for not performing uniformity of dosage units of the finished as required by the official monograph. • Initiation date in the batch analysis and stability data sheets shall be mentioned. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Justification shall be submitted for use of 99.6 potency in the submitted raw data sheets with respect to COA submitted in 3.2.S.4.4 wherein potency of 100 is mentioned. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	

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

242.	Name, address of Applicant / Marketing Authorization Holder	**M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 124/2022-DRAP (AD-199037819226) dated 22-08-2022 issued on the basis of inspection conducted on 16-08-2022 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-37/2003-Lic (Vol-I) dated 19/03/2021 specifying Tablet (General) section (New).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25747, dated 24/10/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 87038772242 dated:

		23/10/2023.
	The proposed proprietary name / brand name	**Onolid 600mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linezolid ……. …… 600mg
	Pharmacotherapeutic Group of (API)	Other antibacterial (J01XX)
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO/DPC.
	Proposed unit price	As per SRO/DPC.
	The status in reference regulatory authorities	ZYVOX® (linezolid) 600mg tablets, USFDA approved.
	For generic drugs (me-too status)	Zylon 600mg Tablet, Getz Pharma, Reg. No. 055439.
	Name and address of API manufacturer.	M/s Optrix Laboratories Private Limited, Survey No. 145/A, 145/AA & 147, Ramalingampally (V), Bommala ramaram (M), Yadadri – Bhuvanagiri (Dist)-508 126, Telangana, India. Firm has submitted copy of GMP certificate No. 5207/TS/2022 dated 14-09-2022 issued by Drugs Control Administration Government of Telangana valid till 14-12-2023.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. OT-LID/12/20/048, Mfg. date 12-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5% RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (OT-LID-S2-002/16, OT-LID-S2-003/16 & OT-LID-S2-004/16)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container

		closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the comparator product i.e. Zoldap 600mg tablets, manufactured by Getz pharma by performing quality tests Identification, weight variation, disintegration time, Uniformity of dosage units, Dissolution & Assay. Results of both the test product and innovator product are comparable. Comparative Dissolution is also performed against the same product i.e. Zoldap 600mg tablets, B. No. ZD505 manufactured by Getz pharma in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). Values of F_2 are in acceptable ranges.
	Analytical method validation/verification of product	Method verification studies are submitted including System suitability, specificity, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Optrix Laboratories Private Limited, Survey No. 145/A, 145/AA & 147, Ramalingampally (V), Bommala ramaram (M), Yadadri – Bhuvanagiri (Dist)-508 126, Telangana, India.		
API Lot No.	OT-LID/12/20/048.		
Description of Pack (Container closure system)	Alu/Alu Blister 0f 2 x 7's tablets with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	
Batch Size	5000 Tablets	5000 Tablets	
Manufacturing Date	08/2022	08/2022	
Date of Initiation	08/2022	08/2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 5207/TS/2022 dated 14-09-2022 issued by Drugs Control Administration Government of Telangana valid till 14-12-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000609 date of renewal w.e.f. 21-03-2022.
2.	1.5.6	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has once again submitted copy of GMP certificate No. 5207/TS/2022 dated 14-09-2022 issued by Drugs Control Administration Government of Telangana valid till 14-12-2023. *Not valid.*
3.		Copies of executed BMR's shall be submitted.	Submitted.
4.	3.2.S.4.1	Specifications of the drug substance provided by the drug product manufacturer are different from that provided by the drug substance manufacturer. Justification shall be submitted.	Firm has submitted that specifications of drug substance by drug product manufacturer are in align with USP specifications.
5.	3.2.S.4.2	Analytical procedures of the drug substance submitted by the drug substance manufacturer are different from USP monograph. Justification shall be submitted.	Firm has submitted that updated analytical method is requested from drug substance manufacturer. However, the firm has performed analysis as per USP method.
6.	3.2.S.4.4	COA of the drug substance from drug substance manufacturer has mentioned in-house specifications while that from drug product manufacturer has mentioned USP specifications. Clarification shall be submitted.	Firm has submitted that all tests were performed as per USP monograph so the conclusion was drafted as USP compliant.
7.	3.2.S.7	• Justification shall be submitted for over writing the real time stability conditions in the submitted stability data sheets for the drug substance. • Real time stability data of the three batches for drug substance as per zone Iva shall be submitted.	*No justification is submitted by the firm against this point.* *No stability data as per Zone Iva is submitted by the firm.*
8.	3.2.P.2.2	• Justification shall be submitted for not performing PE & CDP against the innovator product. • Details of the product i.e. name of manufacturer, batch number, manufacturing date and expiry date etc. against which PE & CDP are performed shall be submitted with clear and visible pictorial evidence.	Firm has referred to CTD guidance document that CDP and PE can be established with reference product or comparator product. Details are as follows; Zoldap 600mg tablets, B. No. ZD505 manufactured by M/s Getz pharma.
9.	3.2.P.8	• Justification shall be submitted for not performing uniformity of	Firm has submitted that as per USP (905) physical tests content uniformity of film coated tablets with strengths of 25mg or

		dosage units of the finished as required by the official monograph. • Initiation date in the batch analysis and stability data sheets shall be mentioned. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Most of the submitted chromatograms does not reflect any wave length. Justification shall be submitted. • Chromatograms with wavelength have shown wavelength of 254nm while official monograph has mentioned 251nm. Justification shall be submitted. • Justification shall be submitted for use of 99.6 potency in the submitted raw data sheets with respect to COA submitted in 3.2.S.4.4 wherein potency of 100 is mentioned. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	less or percentage of API as compared to weight per tablet is 25% or less, is required. Firm has submitted revised stability data sheets with initiation date and is incorporated in stability data. *Firm has submitted copy of commercial invoice No. 2021OT334/EXP dated 21-12-2020 in the name of M/s Biomark pharma mentioning 25kg of Linezolid B. No. OT/LID/12//20/048 attested by Assistant Director DRAP, Lahore dated 30-12-2020.* Firm has submitted that default report format does not provide the time & wavelength details however, from future onwards such details will be the part of chromatograms. Firm has submitted that dissolution test 2 was used which suggest use of 245nm wavelength. Firm has submitted that as identified, mistakenly the potency was taken as 99.6%. However, results measured are will within range during finished product analysis & during its stability. Firm has submitted that HPLC system used for the analysis of trial was not 21CFR compliant. Firm has submitted that no previous approval is available.

Decision: Approved. The firm will submit valid copy of GMP certificate of the drug substance manufacturer.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

243.	Name, address of Applicant / Marketing Authorization Holder	**M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 124/2022-DRAP (AD-199037819226) dated 22-08-2022 issued on the basis of inspection conducted on 16-08-2022 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-37/2003-Lic (Vol-I) dated 19/03/2021 specifying Tablet (General) section (New).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22775, dated 15/09/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 513362841859 dated: 26/07/2023.
	The proposed proprietary name / brand name	**Q-Onston 4mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ondansetron HCl eq. to Ondansetron …. …… 4mg
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists (A04AA)
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO/DPC.
	Proposed unit price	As per SRO/DPC.
	The status in reference regulatory authorities	Zofran 4mg & 8mg film coated tablets, USFDA approved. **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	Ondonex 4mg Tablet, Genix pharma, Reg. No. 081545.
	Name and address of API manufacturer.	M/s CTX Life Sciences Pvt. Ltd., Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P, GIDC, City - Sachin, Dist. - Surat Gujarat State, India. Copy of GMP certificate No. 22063346 dated 30-05-2022 issued by Food and Drugs control Administration Gujrat State, India valid till 29-05-2025 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of

		manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 22ON000051, Mfg. date 04 -2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5% RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (ON130001, ON130002 & ON130003)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the innovator product i.e. Zofran 4mg Tablet, by Novartis pharma by performing quality tests Identification, disintegration time, Uniformity of dosage units, Dissolution & Assay. Results of both the test product and innovator product are comparable. Comparative Dissolution is performed against the comparator brand i.e. Onset tablet 4mg Tablet, B. No. 252, manufacturing date of 07-2018 manufactured by M/s Pharmedic laboratories in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Method verification studies are submitted including System suitability, specificity, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	M/s CTX Life Sciences Pvt. Ltd., Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P, GIDC, City - Sachin, Dist. - Surat Gujarat State, India.		
API Lot No.	22ON000051.		
Description of Pack (Container closure system)	Alu/Alu Blister packing of 1 x 10's.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T1	T2	
Batch Size	5000 Tablets	5000 Tablets	
Manufacturing Date	11/2022	11/2022	
Date of Initiation	11/2022	11/2022	
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22063346 dated 30-05-2022 issued by Food and Drugs control Administration Gujrat State, India valid till 29-05-2025 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate No. E-2942982887261 dated 04-10-2022 mentioning Ondansetron USP 25 Kg, B. No. 22ON500001, Mfg. date 04-2022 from M/s M/s CTX Life Sciences Pvt. Ltd., India. Clearance certificate is for M/s Wimits Pharmaceuticals, Lahore. Firm has also submitted loan letter from M/s M/s Wimits Pharmaceuticals, Lahore wherein they have taken 02kg of Ondansetron for product development.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000609 date of renewal w.e.f. 21-03-2022.
2.	1.5.2	Revise label claim as per reference product with submission of full fee as Ondansetron hydrochloride dihydrate equivalent to 4 mg of ondansetron.	Firm has submitted revised label claim as follows; Each film coated tablet contains: Ondansetron Hydrochloride dihydrate eq. to Ondansetron …. …… 4mg *Fee required for revision of label claim is not submitted.*
3.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.6	COA/details of the working standard used in the development of trial batches shall be submitted.	Firm has submitted copy of COA for working standard. *However, COA is not in readable form. Clear and readable copy of COA of the working standard shall be submitted.*
5.	3.2.S.7	• Justification shall be submitted for over writing the real time stability conditions in the submitted stability data sheets for the drug substance.	*No justification is submitted against this point.* Firm has submitted new stability data sheets for the drug substance.

		• Real time stability data of the three batches for drug substance as per zone Iva shall be submitted.	
6.	3.2.P.2.2	• Details of the innovator product i.e. Batch number, manufacturing date & expiry date etc. against which Pharmaceutical Equivalence is performed shall be submitted with clear and visible pictorial evidence. • Justification shall be submitted for not performing CDP against the innovator brand. • Values of F_2 calculated for all the three mediums shall be submitted. • Justification shall be submitted that how CDP is performed against the product with manufacturing date of 07-2018. • Justification shall be submitted for submission same results of CDP for both the strengths of ondansetron.	Firm has submitted new CDP studies performed against Garvis 4mg Tablets, B. No. 18M121, mfg. date 12-2021, Exp. date 11-2023, manufactured by Bio-Mark Pharmaceuticals (Pvt.) Ltd. *However, no pictorial evidence of the innovator product is submitted by the firm.* *Furthermore, in the initially submitted data it was mentioned that PE studies are performed against the innovator product i.e Zofran 4mg Tablet, by Novartis pharma.* *In the initially submitted data, CDP studies were performed against Onset tablet 4mg Tablet, B. No. 252, manufacturing date of 07-2018 manufactured by M/s Pharmedic laboratories and now the same results are submitted with Garvis 4mg Tablets, B. No. 18M121, mfg. date 12-2021, Exp. date 11-2023, manufactured by Bio-Mark Pharmaceuticals (Pvt.) Ltd.* Firm has submitted that it was a typo mistake and details of the reference product are Garvis 4mg Tablets, B. No. 18M121, mfg. date 12-2021, Exp. date 11-2023, manufactured by Bio-Mark Pharmaceuticals (Pvt.) Ltd. *In the initially submitted data, CDP studies were performed against Onset tablet 4mg Tablet, B. No. 252, manufacturing date of 07-2018 manufactured by M/s Pharmedic laboratories and now the same results are submitted with Garvis 4mg Tablets.* Firm has submitted new CDP results for Q-Onston with Garvis 4mg Tablets, B. No. 18M121, mfg. date 12-2021, Exp. date 11-2023, manufactured by Bio-Mark Pharmaceuticals (Pvt.) Ltd. *However, only the name of the product is changed by the firm while all the data remains the same.*
7.	3.2.P.8	• Results for uniformity of dosage units at each time point shall be submitted instead of writing complies only. • Provide submission of the document for loan of API in DRAP within 30 days as per Notification	Firm has submitted revised stability data sheets with inclusion of results for uniformity of dosage units at each time point. *Firm has submitted a document with subject of "Borrowing of API for ……" Wherein they have borrowed API from*

		No. 14-1/2022-PEC dated 16-01-2023.	*M/s Wimits Pharma and the same document is submitted in DRAP dated 14-02-2023 as per directions of Notification No. 14-1/2022-PEC dated 16-01-2023 within 30 days.*
		• Submitted chromatograms does not reflect any time and wave length. Justification shall be submitted.	Firm has submitted that default format report does not provide the time and wavelength details however, from future onwards such details will be the part of chromatograph.
		• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	HPLC system used for the analysis of the trial was not 21 CFR compliant.
		• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Firm has submitted that no previous approval is available.

Decision: Approved. The firm will submit full fee for revision of formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. before the issuance of registration certificate

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

244.	Name, address of Applicant / Marketing Authorization Holder	**M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 124/2022-DRAP (AD-199037819226) dated 22-08-2022 issued on the basis of inspection conducted on 16-08-2022 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-37/2003-Lic (Vol-I) dated 19/03/2021 specifying Tablet (General) section (New).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20074, dated 15/08/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 3175108585 dated: 02/08/2023.
	The proposed proprietary name / brand name	**Q-Onston 8mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ondansetron HCl eq. to Ondansetron …. …… 8mg

	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists (A04AA)
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO/DPC.
	Proposed unit price	As per SRO/DPC.
	The status in reference regulatory authorities	Zofran 4mg & 8mg film coated tablets, USFDA approved. **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	Welon 8mg Tablet, Werrick pharmaceuticals, Reg. No. 029561.
	Name and address of API manufacturer.	M/s CTX Life Sciences Pvt. Ltd., Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P, GIDC, City - Sachin, Dist. - Surat Gujarat State, India. Copy of GMP certificate No. 22063346 dated 30-05-2022 issued by Food and Drugs control Administration Gujrat State, India valid till 29-05-2025 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 22ON000051, Mfg. date 04 -2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (ON130001, ON130002 & ON130003)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative	Pharmaceutical Equivalence is established against the

	dissolution profile	innovator product i.e. Zofran 8mg Tablet, by Novartis pharma by performing quality tests Identification, disintegration time, Uniformity of dosage units, Dissolution & Assay. Results of both the test product and innovator product are comparable. Comparative Dissolution is performed against the comparator brand i.e. Onset tablet 8mg Tablet, B. No. 246, manufacturing date of 07-2018 manufactured by M/s Pharmedic laboratories in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Method verification studies are submitted including System suitability, specificity, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	M/s CTX Life Sciences Pvt. Ltd., Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P, GIDC, City - Sachin, Dist. - Surat Gujarat State, India.		
API Lot No.	22ON000051.		
Description of Pack (Container closure system)	Alu/Alu Blister packing of 1 x 10's.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T1	T2	
Batch Size	5000 Tablets	5000 Tablets	
Manufacturing Date	11/2022	11/2022	
Date of Initiation	11/2022	11/2022	
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22063346 dated 30-05-2022 issued by Food and Drugs control Administration Gujrat State, India valid till 29-05-2025 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate No. E-2942982887261 dated 04-10-2022 mentioning Ondansetron USP 25 Kg, B. No. 22ON500001, Mfg. date 04-2022 from M/s M/s CTX Life Sciences Pvt. Ltd., India. Clearance certificate is for M/s Wimits Pharmaceuticals, Lahore. Firm has also submitted loan letter from M/s M/s Wimits Pharmaceuticals, Lahore wherein they have taken 02kg of Ondansetron for product development.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000609 date of renewal w.e.f. 21-03-2022.
2.	1.5.2	Revise label claim as per reference product with submission of full fee as Ondansetron hydrochloride dihydrate equivalent to 4 mg of ondansetron.	Firm has submitted revised label claim as follows; Each film coated tablet contains: Ondansetron Hydrochloride dihydrate eq. to Ondansetron …. …… 8mg *Fee required for revision of label claim is not submitted.*
3.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.6	COA/details of the working standard used in the development of trial batches shall be submitted.	Firm has submitted copy of COA for working standard. *However, COA is not in readable form. Clear and readable copy of COA of the working standard shall be submitted.*
5.	3.2.S.7	• Justification shall be submitted for over writing the real time stability conditions in the submitted stability data sheets for the drug substance. • Real time stability data of the three batches for drug substance as per zone Iva shall be submitted.	*No justification is submitted against this point.* Firm has submitted new stability data sheets for the drug substance.
6.	3.2.P.2.2	• Justification shall be submitted for not performing CDP against the innovator brand. • Details of the innovator product i.e. Batch number, manufacturing date & expiry date etc. against which Pharmaceutical Equivalence is performed shall be submitted with clear and visible pictorial evidence.	Firm has referred to CTD guidance document wherein it is mentioned that CDP could be established with reference or comparator product. Details are as follows; Onset – 8mg tablets, B. No. 252, Mfg. date 07-2021 manufactured by Pharmedic Laboratories. *In the initially submitted data it was mentioned that PE studies are performed against the innovator product i.e Zofran 4mg Tablet, by Novartis pharma.* *In the initially submitted data, CDP studies were performed against Onset tablet 8mg Tablet, B. No. 246, manufacturing date of 07-2018*

		• Values of F_2 calculated for all the three mediums shall be submitted. • Justification shall be submitted that how CDP is performed against the product with manufacturing date of 07-2018. • Justification shall be submitted for submission same results of CDP for both the strengths of ondansetron.	*manufactured by M/s Pharmedic laboratories.* Submitted. Firm has submitted that it was typo mistake. *No justification is submitted by the firm.*
7.	3.2.P.8	• Results for uniformity of dosage units at each time point shall be submitted instead of writing complies only. • Provide submission of the document for loan of API in DRAP within 30 days as per Notification No. 14-1/2022-PEC dated 16-01-2023. • Submitted chromatograms does not reflect any time and wave length. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Submitted. *Firm has submitted a document with subject of "Borrowing of API." Wherein they have borrowed API from M/s Wimits Pharma and the same document is submitted in DRAP dated 14-02-2023 as per directions of Notification No. 14-1/2022-PEC dated 16-01-2023 within 30 days.* Firm has submitted that default report format does not provide the time & wavelength details however, from future onwards such details will be the part of chromatograms. Firm has submitted that HPLC system used for the analysis of trial was not 21CFR compliant. Firm has submitted that no previous approval is available.

Decision: Approved with following label claim;

"Each film coated tablet contains:

Ondansetron Hydrochloride dihydrate eq. to Ondansetron …. …… 8mg"

- **Registration letter will be issued after Submission COA/details of the working standard used in the development of trial batches and fee of Rs. 30,000/- for correction/pre-approval revision of formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

245.	Name, address of Applicant / Marketing Authorization Holder	**M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Copy of GMP certificate No. 124/2022-DRAP (AD-199037819226) dated 22-08-2022 issued on the basis of inspection conducted on 16-08-2022 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-37/2003-Lic (Vol-I) dated 19/03/2021 specifying Sachet (General) section (New).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22776, dated 15/09/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 35439519573 dated: 12/09/2023.
	The proposed proprietary name / brand name	**Qkast 4mg sachet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains: Montelukast Sodium eq. to Montelukast. …… 4mg
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists. (R03DC)
	Pharmaceutical form of applied drug	Oral Granules in Sachet.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO/DPC.
	Proposed unit price	As per SRO/DPC.
	The status in reference regulatory authorities	Singulair 4mg sachet, USFDA approved.
	For generic drugs (me-too status)	Lucast 4mg sachet, AGP Limited, Reg. No. 048716.
	Name and address of API manufacturer.	M/s Morepen Laboratories Limited, Village-Masulkhana, Parwanoo, Distt. Solan (H.P.) India. Copy of GMP certificate No. HFW-H (Drugs) 93/91 dated 05-01-2023 issued on the basis of inspection conducted on 10th & 11th march, 2021 valid till 11-05-2024.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. MK14-2520, Mfg. date 04-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C / 65% RH for 24 months Accelerated: 40°C / 75% RH for 06 months Batches: (MTN14-8015, MTN14-0060 & MTN14-0061)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the innovator brand Singulair 4mg sachet by performing quality tests Identification, weight variation, Content Uniformity, Dissolution & Assay. Results of both the test product and innovator product are comparable. Comparative Dissolution is also performed against the same product i.e. Singulair 4mg sachet in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). Values of F_2 are in acceptable ranges.
	Analytical method validation/verification of product	Method verification studies are submitted including System suitability, specificity, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Morepen Laboratories Limited, Village-Masulkhana, Parwanoo, Distt. Solan (H.P.) India.		
API Lot No.	MK14-2550.		
Description of Pack (Container closure system)	White to off white granular powder packed in sealed printed foil sachet (14 x 1's) packed in unit carton with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	5000 Sachets	5000 Sachets	5000 Sachets
Manufacturing Date	07/2022	07/2022	07/2022
Date of Initiation	17/07/2022	18/07/2022	19/07/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HFW-H (Drugs) 93/91 dated 05-01-2023 issued on the basis of inspection conducted on 10th & 11th march, 2021 valid till 11-05-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate No. E-1457929343156 dated 19-06-2022 mentioning Montelukast Sodium USP 10 Kg, B. No. MK14-2520, Mfg. date 04-2022 from M/s Morepen Laboratories Limited India.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML no. 000609 date of renewal w.e.f. 21-03-2022.
2.	2.3	Table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	Firm has submitted revised table for literature references. *However, fee applicable for pre-registration variation is not submitted.*
3.	3.2.S.4.1	Specifications of the drug substance from drug substance manufacturer are different from the specifications provided by the drug product manufacturer. Justification shall be submitted.	Firm has submitted that the API manufacturer has developed and tested the API a per USP specifications. The drug product manufacturer has also the specifications as per USP. Most of the specifications from both drug substance and drug product are same and according to USP. However, the API manufacturer has performed some additional tests based on in-house specifications which are not similar to drug product manufacturer specifications.
4.	3.2.S.4.4	Specifications mentioned in the submitted COA by the drug substance manufacturer are different from the specifications submitted by drug substance manufacturer. Justification shall be submitted.	Firm has submitted that the API manufacturer has developed and tested the API a per USP specifications. The drug product manufacturer has also the specifications as per USP. Most of the specifications from both drug substance and drug product are same and according to USP. However, the API manufacturer has performed some additional tests based on in-house specifications which are not similar to drug product manufacturer specifications. *However, the firm was asked that Specifications mentioned in the submitted COA by the drug substance*

			manufacturer are different from the specifications submitted by drug substance manufacturer. The firm didn't answer the same.
5.	3.2.S.5	Details/COA of the reference standard/working standard used in the analysis of the development studies shall be submitted.	Firm has submitted USP Lot Number R10590 as reference standard.
6.	3.2.P.2.2	Details of the innovator product against which CDP & PE studies are performed i.e. name of manufacturer, batch number, manufacturing date, expiry date etc. shall be submitted with clear and visible pictorial evidence.	Firm has submitted details of the innovator product as follows; Singulair 4mg Sachet, B. No. J005308, mfg. date 01-2020, Exp. date 01-2023 manufactured by Merck & Co Inc. Firm has also submitted a picture of the Singulair sachet. *However, from the picture details are not visible.*
7.	3.2.P.5.3	Justification shall be submitted for not covering the concentration mentioned in the monograph i.e. 0.24mg/ml in the accuracy studies of the analytical method verification of the product.	Firm has submitted that as the monograph of montelukast sachet is available in USP and the method defined is validated. As per USP guidelines the verification studies of the pharmacopoeial products does not require the linearity test as the pharmacopoeial method are linear. If we draw the graph of concentration used in accuracy and recovery, we get linear graph (R^2 = 0.9999) so it can be concluded that the method is validated with the concentration used.
8.		• Stability data sheets as per decision of Registration Board with inclusion of API lot number and condition of stability studies shall be submitted. • Results for uniformity of dosage units at each time point shall be submitted instead of writing complies only. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Submitted chromatograms does not reflect any wave length. Justification shall be submitted.	Firm has submitted revised stability data sheets with inclusion of API lot No. MK14-2550 and inclusion of Results for uniformity of dosage units at each time point. Submitted. Firm has submitted that the chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is not 21CFR compliant. Firm has submitted that no previous approval is available. Firm has submitted that the chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that wavelength which was set in the method.

			The wavelength is mentioned in the standard analytical procedure of the product.

Decision: Approved. Registration letter will be issued after submission Rs. 7,500/- for correction/pre-approval changes as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

246.	Name, address of Applicant / Marketing Authorization Holder	**M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 124/2022-DRAP (AD-199037819226) dated 22-08-2022 issued on the basis of inspection conducted on 16-08-2022 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-37/2003-Lic (Vol-I) dated 19/03/2021 specifying Tablet (General) section (New).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25748, dated 24/10/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 71443285 dated: 16/10/2023.
	The proposed proprietary name / brand name	**Qutine 10mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ebastine ……. …… 10mg
	Pharmacotherapeutic Group of (API)	Other antihistamines for systemic use. (R06AX)
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	JP specification.
	Proposed Pack size	As per SRO/DPC.
	Proposed unit price	As per SRO/DPC.
	The status in reference regulatory authorities	Kestine 10mg film coated tablets, ANSM approved.
	For generic drugs (me-too status)	Zebastine 1omg tablets, Zeta pharma, Reg. No. 108314.
	Name and address of API manufacturer.	M/s Morepen Laboratories Limited, Village-Masulkhana, Parwanoo, Distt. Solan (H.P.) India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form,

		manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. EBSN/2210001, Mfg. date 01-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (EB/1610005, EB/1610006 & EB/1610007)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Kestine 10mg Tablet, B. No. 313748, Mfg. date 12-2021 by performing quality tests Identification, weight variation, disintegration time, Uniformity of dosage units, Dissolution & Assay. Results of both the test product and innovator product are comparable. Comparative Dissolution is also performed against the same product i.e. Kestine 10mg Tablet in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). Values of F_2 are in acceptable ranges.
	Analytical method validation/verification of product	Method verification studies are submitted including System suitability, specificity, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	M/s R.L. Fine Chem (Pvt.) Ltd., No. 15, KBH Industrial Area, Yelahanka, Banglore, Karanataka, India.
API Lot No.	EBSN/2210001.
Description of Pack (Container closure system)	Alu/PVC Blister further packed in printed unit Carton.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	T001	T002	T003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	08/2022	08/2022	08/2022
Date of Initiation	12/08/2022	13/08/2022	14/08/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HFW-H (Drugs) 93/91 dated 05-01-2023 issued on the basis of inspection conducted on 10th & 11th march, 2021 for M/s Morepen Laboratories Limited, Village-Masulkhana, Parwanoo, Distt. Solan (H.P.) India valid till 11-05-2024. ***Not for the source of drug substance.***
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form clearance certificate No. E-1433986221657 dated 03-06-2022 mentioning Ebastine BP 10 Kg, B. No. EBSN/2210001, Mfg. date 01-2022 from M/s R.L. Fine Chem Pvt., Ltd., No. 15, KBH Industrial area, Yelahanka, Bingalore, Karanataka, India. Clearance certificate is for M/s Epharm Laboratories. Firm has also submitted loan letter from M/s Epharm Laboratories wherein they have taken 100gm of Ebastine for product development.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML no. 000609 date of renewal w.e.f. 21-03-2022.
2.	1.5.6	Submitted GMP has mentioned Montelukast sodium, Desloratadine & Loratadine while the imported drug substance is not mentioned in the GMP. Clarification shall be submitted.	Firm has submitted copy of certificate No. HMF07-15031/147/2022-AD-DCA issued by DCA Chuttugunta, Guntur (AP) dated 18-08-2022 with a validity of 03 years.
3.	2.3	Table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	Firm has submitted revised table for literature references. *However, fee applicable for pre-registration variation is not submitted.*
4.	3.2.S.2.1	This section has mentioned M/s R. L. Fine Chem Pvt., Ltd, India as manufacturer of the drug substance	Firm has submitted that mistakenly GMP of M/s Morepen Pharma was attached. Firm has also submitted new GMP

		which is in contrast to 1.5.6. clarification shall be submitted.	certificate for the drug substance manufacturer.
5.	3.2.S.4.1	Specifications of the drug substance from drug substance manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.2	Analytical procedures of the drug substance from drug substance manufacturer shall be submitted.	Submitted.
7.	3.2.S.5	Details/COA of the reference standard/working standard used in the analysis of the development studies shall be submitted.	Firm has submitted COA of the working standard with B. No. EB/1809004.
8.	3.2.S.7	• Justification shall be submitted for over writing the real time stability conditions in the submitted stability data sheets for the drug substance. • Real time stability data of the three batches for drug substance as per zone Iva shall be submitted.	Firm has submitted that the stability data sheets were not over written, however, while copying data to the dossiers the format was disturbed from normal. *However, in the submitted stability data sheets of the drug substance, the real time stability data condition is overwritten.* Submitted.
9.	3.2.P.2.2	Details of the product i.e. name of manufacturer against which PE & CDP are performed shall be submitted with clear and visible pictorial evidence.	Firm has submitted details of the innovator product as follows; Kestine 10mg tablets, B. No. A036061, mfg. date 01-2022, Exp. date 12-2025 manufactured by Laboratorious Almirall S.A. Firm has also submitted a picture of the Kestine 10mg tablets. *However, from the picture details are not visible.*
10.	3.2.P.5.1	Justification shall be submitted for NMT 60 minutes time for disintegration in the specification.	Firm has submitted that specifications of qutine tablets are from Japanese pharmacopoeia. According to Japanese Pharmacopoeia general chapter '6.09 Disintegration test the time for disintegration of coated tablets and pills is 60 minutes unless otherwise specified in individual monograph.
11.	3.2.P.8	• Stability data sheets as per decision of Registration Board with inclusion of API lot number and condition of stability studies shall be submitted. • Results for uniformity of dosage units at each time point shall be submitted instead of writing complies only. • Provide submission of the document for loan of API in DRAP within 30 days as per Notification No. 14-1/2022-PEC dated 16-01-2023.	Firm has submitted revised stability data sheets with inclusion of API lot No. EBSN/2210001 and inclusion of Results for uniformity of dosage units at each time point. Submitted. *Firm has submitted a document with subject of "Borrowing of API." Wherein they have borrowed API from M/s Epharm Laboratories, Karachi and the same document is submitted in DRAP dated 15-02-2023 as per directions of Notification*

		• Valid copy of GMP certificate of the drug substance manufacturer issued by concerned/relevant regulatory authority shall be submitted. • Submitted chromatograms does not reflect any time and wave length. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	*No. 14-1/2022-PEC dated 16-01-2023 within 30 days.* Submitted. Firm has submitted that the chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that wavelength which was set in the method. The wavelength is mentioned in the standard analytical procedure of the product. Firm has submitted that the chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is not 21CFR compliant. Firm has submitted that no previous approval is available.

Decision: Approved. Registration letter will be issued after submission Rs. 7,500/- for correction/pre-approval changes as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

247.	Name, address of Applicant / Marketing Authorization Holder	**M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 124/2022-DRAP (AD-199037819226) dated 22-08-2022 issued on the basis of inspection conducted on 16-08-2022 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-37/2003-Lic (Vol-I) dated 19/03/2021 specifying Tablet (General) section (New).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25749, dated 24/10/2023.

	Details of fee submitted	PKR 30,000/- vide slip No. 0740501823 dated: 16/10/2023.
	The proposed proprietary name / brand name	**Qutine 20mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ebastine ……. …… 20mg
	Pharmacotherapeutic Group of (API)	Other antihistamines for systemic use. (R06AX)
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	JP specification.
	Proposed Pack size	As per SRO/DPC.
	Proposed unit price	As per SRO/DPC.
	The status in reference regulatory authorities	Kestine 20mg film coated tablets, (Netherland approved)
	For generic drugs (me-too status)	Utine 20mg tablets, Uni-Tiech pharmaceutical, Reg. No. 067311.
	Name and address of API manufacturer.	M/s Morepen Laboratories Limited, Village-Masulkhana, Parwanoo, Distt. Solan (H.P.) India. Copy of GMP certificate No. HFW-H (Drugs) 93/91 dated 05-01-2023 issued on the basis of inspection conducted on 10th & 11th march, 2021 valid till 11-05-2024.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. EBSN/2210001, Mfg. date 01-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5% RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (EB/1610005, EB/1610006 & EB/1610007)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Kestine 20mg Tablet, B. No. 31369, Mfg. date 12-2021 by performing quality tests Identification, weight variation, disintegration time, Uniformity of dosage units, Dissolution & Assay. Results of both the test product and innovator product are comparable. Comparative Dissolution is also performed against the same product i.e. Kestine 20mg Tablet in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). Values of F_2 are in acceptable ranges.
	Analytical method validation/verification of product	Method verification studies are submitted including System suitability, specificity, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	M/s R.L. Fine Chem (Pvt.) Ltd., No. 15, KBH Industrial Area, Yelahanka, Banglore, Karanataka, India.		
API Lot No.	EBSN/2210001.		
Description of Pack (Container closure system)	Alu/PVC Blister further packed in printed unit Carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T004	T005	T006
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	08/2022	08/2022	08/2022
Date of Initiation	12/08/2022	13/08/2022	14/08/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HFW-H (Drugs) 93/91 dated 05-01-2023 issued on the basis of inspection conducted on 10th & 11th march, 2021 for M/s Morepen Laboratories Limited, Village-Masulkhana, Parwanoo, Distt. Solan (H.P.) India valid till 11-05-2024. ***Not for the source of drug substance.***
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form clearance certificate No. E-1433986221657 dated 03-06-2022 mentioning Ebastine BP 10 Kg, B. No. EBSN/2210001, Mfg. date 01-2022 from M/s R.L. Fine Chem Pvt., Ltd., No. 15, KBH Industrial area, Yelahanka, Bingalore, Karanataka, India. Clearance certificate is for M/s Epharm Laboratories. Firm has also submitted loan letter from M/s Epharm Laboratories wherein they have taken 100gm of Ebastine for product development.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML no. 000609 date of renewal w.e.f. 21-03-2022.
2.	1.5.6	Submitted GMP has mentioned Montelukast sodium, Desloratadine & Loratadine while the imported drug substance is not mentioned in the GMP. Clarification shall be submitted.	Firm has submitted copy of certificate No. HMF07-15031/147/2022-AD-DCA issued by DCA Chuttugunta, Guntur (AP) dated 18-08-2022 with a validity of 03 years.
3.	2.3	Table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	Firm has submitted revised table for literature references. *However, fee applicable for pre-registration variation is not submitted.*
4.	3.2.S.2.1	This section has mentioned M/s R. L. Fine Chem Pvt., Ltd, India as manufacturer of the drug substance which is in contrast to 1.5.6. clarification shall be submitted.	Firm has submitted that mistakenly GMP of M/s Morepen Pharma was attached. Firm has also submitted new GMP certificate for the drug substance manufacturer.
5.	3.2.S.4.1	Specifications of the drug substance from drug substance manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.2	Analytical procedures of the drug substance from drug substance manufacturer shall be submitted.	Submitted.
7.	3.2.S.5	Details/COA of the reference standard/working standard used in the analysis of the development studies shall be submitted.	Firm has submitted COA of the working standard with B. No. EB/1809004.
8.	3.2.S.7	• Justification shall be submitted for over writing the real time stability conditions in the submitted stability data sheets for the drug substance. • Real time stability data of the three batches for drug substance as per zone Iva shall be submitted.	Firm has submitted that the stability data sheets were not over written, however, while copying data to the dossiers the format was disturbed from normal. *However, in the submitted stability data sheets of the drug substance, the real time stability data condition is overwritten.* Submitted.
9.	3.2.P.2.2	Details of the product i.e. name of manufacturer against which PE & CDP are performed shall be	*Not submitted.*

		submitted with clear and visible pictorial evidence.	
10.	3.2.P.5.1	Justification shall be submitted for NMT 60 minutes time for disintegration in the specification.	Firm has submitted that specifications of qutine tablets are from Japanese pharmacopoeia. According to Japanese Pharmacopoeia general chapter'6.09 Disintegration test' the time for disintegration of coated tablets and pills is 60 minutes unless otherwise specified in individual monograph.
11.		• Stability data sheets as per decision of Registration Board with inclusion of API lot number and condition of stability studies shall be submitted. • Results for uniformity of dosage units at each time point shall be submitted instead of writing complies only. • Provide submission of the document for loan of API in DRAP within 30 days as per Notification No. 14-1/2022-PEC dated 16-01-2023. • Valid copy of GMP certificate of the drug substance manufacturer issued by concerned/relevant regulatory authority shall be submitted. • Submitted chromatograms does not reflect any time and wave length. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Firm has submitted revised stability data sheets with inclusion of API lot No. EBSN/2210001 and inclusion of Results for uniformity of dosage units at each time point. Submitted. *Firm has submitted a document with subject of "Borrowing of API for ……." Wherein they have borrowed API from M/s Epharm Laboratories, Karachi and the same document is submitted in DRAP dated 15-02-2023 as per directions of Notification No. 14-1/2022-PEC dated 16-01-2023 within 30 days.* Submitted. Firm has submitted that the chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that wavelength which was set in the method. The wavelength is mentioned in the standard analytical procedure of the product. Firm has submitted that the chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is not 21CFR compliant. Firm has submitted that no previous approval is available.

Decision: Approved. Registration letter will be issued after submission Rs. 7,500/- for correction/pre-approval changes as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
248.	Name, address of Applicant / Marketing Authorization Holder	**M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper (Pvt.) Ltd., 26-A Small Industrial Estate Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 124/2022-DRAP (AD-199037819226) dated 22-08-2022 issued on the basis of inspection conducted on 16-08-2022 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-37/2003-Lic (Vol-I) dated 19/03/2021 specifying Tablet (General) section (New).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23861, dated 28/09/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 862835139766 dated: 25/09/2023.
	The proposed proprietary name / brand name	**Topride 50mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Itopride hydrochloride ……. …… 50mg
	Pharmacotherapeutic Group of (API)	Propulsive/Gastroprokinetic. (A03FA)
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	Innovator specification.
	Proposed Pack size	As per SRO/DPC.
	Proposed unit price	As per SRO/DPC.
	The status in reference regulatory authorities	Ganaton Tablets 50mg, PMDA approved.
	For generic drugs (me-too status)	Itokine 50mg Tablet, Hilton Pharma, Reg. No. 034663.
	Name and address of API manufacturer.	M/s Vasudha Pharma Chem Limited, Unit-III Plot No. 23 & 24, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam-531019, Andra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug

		product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. CITP/2012008, Mfg. date 07-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (CITP/14002, CITP/14003 & CITP/14004)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Ganaton 50mg Tablet by performing quality tests Identification, weight variation, disintegration time, Uniformity of dosage units, Dissolution & Assay. Results of both the test product and innovator product are comparable. Comparative Dissolution is also performed against the same product i.e. Ganaton 50mg Tablet in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). Values of F_2 are in acceptable ranges.
	Analytical method validation/verification of product	Method verification studies are submitted including System suitability, specificity, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Vasudha Pharma Chem Limited, Unit-III Plot No. 23 & 24, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam-531019, Andra Pradesh, India.		
API Lot No.	.		
Description of Pack (Container closure system)	Alu/Alu Blister further packed in bleach card unit Carton along with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	10/2022	10/2022	10/2022

Date of Initiation	25/10/2022	26/10/2022	27/10/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate for Morepen Laboratories Limited is submitted instead of M/s Vasudha Pharma Chem Limited.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. 0208/U3/E/20-21 dated 05-01-2021 mentioning Itopride HCl in-house 25 Kg, B. No. CITP/2012008, Mfg. date 07-2020 from M/s Vasudha pharma chem limited., India. Invoice is attested by Assistant Director, I&E, DRAP, Lahore dated 21-01-2021. Clearance certificate is for M/s Wimits Pharmaceuticals, Lahore. Firm has also submitted loan letter from M/s M/s Wimits Pharmaceuticals, Lahore wherein they have taken 01kg of Itopride HCl for product development.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML no. 000609 date of renewal w.e.f. 21-03-2022.
2.	1.5.6	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of certificate No. HMF07-14051/1203/2021-ADMIN-DCA issued by DCA Chuttugunta, Guntur (AP) dated 13-12-2021 with a validity of 03 years.
3.	2.3.R	Executed copies of BMR's shall be submitted.	Submitted.
4.	3.2.S.4.3	• Justification shall be submitted regarding the Accuracy parameter of the method verification studies wherein 80mg/ml of the analyte is analyzed and 79mcg/ml amount is recovered. • Justification shall be submitted for not covering the concentration mentioned in the analytical method of the drug substance 0.2mg/ml in the accuracy studies of the analytical	Firm has submitted that as per standard analytical procedure the amount analyzed is 80mcg/ml and the amount recovered is 79mcg/ml. 80mg/ml was due to typographic error and instead of 80mcg/ml 80mg/ml was written. Firm has submitted that in-house method of analysis for Itopride was developed and validated for use. The validated method shows linearity results which are in concordant with the USP/ICH

		method verification of the drug substance.	guidelines of method validation. If we draw the graph of concentration used in accuracy and recovery, we get linear graph (R^2 = 0.9999) so it can be concluded that the method is validated with the concentration used.
5.	3.2.S.7	• Clear and readable copies of the stability studies of drug substance as per Zone Iva shall be submitted. • Assay of the drug substance in stability data sheets is by potentiometric method while the specification has mentioned HPLC method for assay test. Clarification shall be submitted.	Submitted. Firm has submitted that API manufacturer initiated the accelerated and real time stability studies of the drug substance in 2014 onward. At that time the potentiometric titration method was used for the analysis of the drug substance. Later, the firm has updated the standard analytical procedure and developed HPLC method for the assay and related substances. The HPLC method was validated by the drug substance manufacturer.
6.	3.2.P.2.2	Details of the product i.e. name of manufacturer, batch number, manufacturing date and expiry date etc. against which PE & CDP are performed shall be submitted with clear and visible pictorial evidence.	Firm has submitted details of the innovator product as follows; Ganaton 50mg tablets, B. No. C15316, mfg. date 09-2021, Exp. date 08-2024 manufactured by Abbott Laboratories.
7.	3.2.P.5.3	Method validation studies including all the parameters of validation shall be submitted.	Submitted.
8.	3.2.P.8	• Stability data sheets as per decision of Registration Board with inclusion of API lot number shall be submitted. • Results for uniformity of dosage units at each time point shall be submitted instead of writing complies only. • Initiation date in the batch analysis and stability data sheets are different from each other. Justification shall be submitted. • Provide submission of the document for loan of API in DRAP within 30 days as per Notification No. 14-1/2022-PEC dated 16-01-2023.	Firm has submitted revised stability data sheets with inclusion of API lot No. CITP/2012008EBSN/2210001 and inclusion of Results for uniformity of dosage units at each time point. Submitted. Firm has submitted that due to typographic mistake, the date in the batch analysis were entered wrong. The correct date is mentioned in the stability data summary sheets, as these dates are also confirmed from the chromatograms of relevant testing interval. *Firm has submitted a document with subject of "Borrowing of API" Wherein they have borrowed API from M/s Wimits Pharma and the same document is submitted in DRAP dated 14-02-2023 as per directions of Notification No. 14-1/2022-PEC dated 16-01-2023 within 30 days.*

		• Submitted chromatograms does not reflect any wave length. Justification shall be submitted.	Firm has submitted that the chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The wavelength was set in the method and saved to that method set. The product was run on that wavelength which was set in the method. The wavelength is mentioned in the standard analytical procedure of the product.
		• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted that the chromatograms were obtained from "Waters" HPLC which is having the software "Empower 2". The software is not 21CFR compliant.
		• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Firm has submitted that no previous approval is available.

Decision: Approved. Registration letter will be issued after submission Rs. 30,000/- for typo errors in the application.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case No. 02. Registration applications of locally manufactured Routine cases on form 5F.

249.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories (Pvt.) Ltd., 16-km, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories (Pvt.) Ltd., 16-km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 93/2020-DRAP (AD-2003099-790) dated 09-06-2020 issued on the basis of inspection conducted on 04-02-2020.
	Evidence of approval of manufacturing facility	Not submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales.
	Dy. No. and date of submission	Form-5F Dy. No. 22879 dated 12-08-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 388904946 dated 20-06-2022.
	The proposed proprietary name / brand	**Jargin 10mg tablets.**

	name	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Empagliflozin …….…. 10mg
	Pharmaceutical form of applied drug	Fil coated tablet.
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors (A10BK)
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	10's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	JARDIANCE contains 10 mg or 25 mg of Empagliflozin, USFDA approved.
	For generic drugs (me-too status)	Diampa Tablets, Getz pharma, Reg. No. 093073.
	Name and address of API manufacturer.	Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Taizhou City, Zhejiang Province, China. Copy of GMP certificate No. ZJ20190132 dated 21-11-2019 valid till 20-11-2024 is submitted by the firm. Firm has also submitted copy of drug manufacturing authorization certificate valid till 16-06-2025.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analyses (432-020-19 mfg. date 09-2019) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions and batches: Real time: 30°C ± 2°C / 65% ± 5% RH for 03 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 03 months Batches: (13900-211201, 13900-211202 & 13900-211203)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, pharmaceutical development, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Brand i.e. Diampa 10mg tablets, B. No. 014FB5 manufactured by M/s Getz Pharma by performing quality tests (Disintegration, Assay, and Dissolution). CDP is also performed against the same brand that is Diampa 10mg tablets, B. No. 014FB5 manufactured by M/s Getz Pharma in Acid media (0.1N HCl), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). In all the three mediums both the applied formulation and comparator product have shown more than 85% release within 15 minutes.
	Analytical method validation/verification of product	Method validation studies have been submitted including: Accuracy, precision, linearity and specificity.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Taizhou City, Zhejiang Province, China.		
API Lot No.	432-020-19.		
Description of Pack (Container closure system)	Alu-Alu blister pack of 1 x 10's further packed in a carton with insertion of leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0,3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EMP10-TR005	EMP10-TR006	EMP10-TR007
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	04-2021	04-2021	09-2021
Date of Initiation	19-05-2021	19-05-2021	21-10-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. ZJ20190132 dated 21-11-2019 valid till 20-11-2024 is submitted by the firm.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate No. E-1038548487861 dated 29-04-2022 mentioning 1.5 kg of Empagliflozin B. No. 13900-211202, mfg. date of 02-01-2022. 3.2.S.4.4 and stability data sheets have mentioned batch number 432-020-19 for the drug substance.

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

Remarks OF Evaluator:

Sr. No.	Section No.	Observation	Response by the firm
1.	1.3.4	• Valid copy of DML of the applicant shall be submitted as the provided one is w.e.f. 07-04-2010. • Valid copy of GMP certificate/last inspection report conducted within last three years shall be submitted.	Firm has submitted copy of application for renewal of DML dated 23-02-2015 and 29-01-2019. *However, last renewal is w.e.f. 07-04-2010.* Firm has also submitted copy of applications for issuance of GMP certificate dated 10-03-2022, 26-05-2023 & 20-03-2023. *However, GMP certificate provided has mentioned inspection date of 04-02-2020.*
2.	1.3.5	Evidence of approval of manufacturing facility/section approval from licensing authority shall be submitted.	GMP certificate has mentioned Tablet non antibiotic section. *However, no section approval letter is submitted.*
3.	3.2.S.4.1	Specification by the drug substance manufacturer has mentioned limit for residue on ignition of NMT 0.1% while the drug product manufacturer has mentioned NMT 0.5%. clarification shall be submitted.	Firm has submitted revised specifications for the drug substance wherein they have changed limits of residue on ignition from NMT 0.5% to NMT 0.1%. *Fee required for change in specification is not submitted.*
4.	3.2.S.4.2	Chromatographic conditions in the analytical method provided by the drug substance manufacturer i.e. λ max 275nm, column temperature 40 ˚C, injection volume 80µl, diluent composition (20:80) and mobile phase (acetonitrile and distilled water) are completely different from that provided by the drug product manufacturer i.e. λ max 223nm, column temperature 30 ˚C, injection volume 10µl, diluent composition (60:40) and mobile phase of acetonitrile and distilled water. Clarification shall be submitted.	Firm has submitted revised analytical method for drug substance as per parameters of the drug substance manufacturer. *No clarification is submitted.*
5.	3.2.S.4.3	Verification of analytical procedures performed by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.4	• Provide results of analysis of relevant batch(es) of Drug Substance performed	Submitted.

		by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance/Active Pharmaceutical Ingredient manufacture. • COA of the drug substance submitted by the finished product manufacturer has mentioned Shanghai YST pharma Co., Ltd., as manufacturer. Clarification shall be submitted.	Firm has submitted new COA of the drug substance wherein they have mentioned Zhejiang Tianyu Pharma as manufacturer.
7.	3.2.S.7.3	Complete real time and accelerated stability studies for the three batches of the drug substance shall be submitted.	Firm has submitted new stability data sheets for the drug substance. Real time: 30˚C ± 2˚C / 65% ± 5% RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 06 months Batches: (13900-211201, 13900-211202 & 13900-211203)
8.	3.2.P.2.2	• Justification shall be submitted for not performing pharmaceutical equivalence studies and CDP against the innovator product. • Justification shall be submitted for performing only three tests in pharmaceutical equivalence studies.	Firm has submitted that CDP is performed against the brand leader. Firm has submitted revised pharmaceutical equivalence studies report with all the tests.
9.	3.2.P.5.2	Analytical procedure in dissolution test has mentioned rotation speed of 50rpm and time of 30 minutes while the review of the innovator product has mentioned 75rpm and 15 minutes' time. Justification shall be submitted.	Firm has submitted revised specifications as per innovator product i.e. 75rpm and 15 minutes' time in dissolution test.
10.	3.2.P.8	• Justification shall be submitted for not performing content uniformity test in stability studies. • Analytical method for the assay test has mentioned to take 50mg of working standard and sample while the raw data sheets have mentioned 25mg of both. Clarification shall be submitted. • Documents for the procurement of API used in the development studies with approval from DRAP (in case of import) shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Firm has submitted that content uniformity test is not a stability parameter. Firm has submitted revised stability reports wherein they have used 50 mg of sample and standard. *However, in the initially submitted data they used 25mg of both sample and standard.* Firm has submitted copy of commercial invoice No. YST19187A mentioning 450gm of Empagliflozin attested by Assistant Director I&E, DRAP, Lahore dated 14-02-2020. Copy of form 3 and Form 7 are also submitted. *No reply submitted.*

Decision: Approved. Registration letter will be issued after Submission Rs. 30,000/- for revision in most of the replies in the application and confirmation of GMP status.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
250.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories (Pvt.) Ltd., 16-km, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories (Pvt.) Ltd., 16-km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 93/2020-DRAP (AD-2003099-790) dated 09-06-2020 issued on the basis of inspection conducted on 04-02-2020.
	Evidence of approval of manufacturing facility	Not submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales.
	Dy. No. and date of submission	Form-5F Dy. No. 22880 dated 12-08-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 348554492342 dated 20-06-2022.
	The proposed proprietary name / brand name	**Jargin 25mg tablets.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Empagliflozin …….…. 25mg
	Pharmaceutical form of applied drug	Fil coated tablet.
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors (A10BK)
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	10's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	JARDIANCE contains 10 mg or 25 mg of Empagliflozin, USFDA approved.
	For generic drugs (me-too status)	Diampa 25mg Tablets, Getz pharma, Reg. No. 093074.
	Name and address of API manufacturer.	Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Taizhou City, Zhejiang Province, China. Copy of GMP certificate No. ZJ20190132 dated 21-11-2019 valid till 20-11-2024 is submitted by the firm. Firm has also submitted copy of drug manufacturing authorization certificate valid till 16-06-2025.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.

		Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analyses (432-020-19 mfg. date 09-2019) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions and batches: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 03 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 03 months Batches: (13900-211201, 13900-211202 & 13900-211203)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, pharmaceutical development, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Brand i.e. Diampa 25mg tablets, B. No. 018FB6, mfg. date 12-2020 manufactured by M/s Getz Pharma by performing quality tests (Disintegration, Assay, and Dissolution). CDP is also performed against the same brand that is Diampa 25mg tablets, B. No. 018FB6, mfg. date 12-2020 manufactured by M/s Getz Pharma in Acid media (0.1N HCl), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). In all the three mediums both the applied formulation and comparator product have shown more than 85% release within 15 minutes.
	Analytical method validation/verification of product	Method validation studies have been submitted including: Accuracy, precision, linearity and specificity.

STABILITY STUDY DATA	
Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Taizhou City, Zhejiang Province, China.
API Lot No.	432-020-19.
Description of Pack (Container closure system)	Alu-Alu blister pack of 1 x 10's further packed in a carton with insertion of leaflet.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 12 months

	Accelerated: 06 months		
Frequency	Accelerated: 0,3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	EMP25-TR005	EMP25-TR006	EMP25-TR007
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	21-01-2021	11-01-2022	21-01-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. ZJ20190132 dated 21-11-2019 valid till 20-11-2024 is submitted by the firm.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate No. E-1038548487861 dated 29-04-2022 mentioning 1.5 kg of Empagliflozin B. No. 13900-211202, mfg. date of 02-01-2022. 3.2.S.4.4 and stability data sheets have mentioned batch number 432-020-19 for the drug substance.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section No.	Observation	Response by the firm
1.	1.3.4	• Valid copy of DML of the applicant shall be submitted as the provided one is w.e.f. 07-04-2010. • Valid copy of GMP certificate/last inspection report conducted within last three years shall be submitted.	Firm has submitted copy of application for renewal of DML dated 23-02-2015 and 29-01-2019. *However, last renewal is w.e.f. 07-04-2010.* Firm has also submitted copy of applications for issuance of GMP certificate dated 10-03-2022, 26-05-2023 & 20-03-2023. *However, GMP certificate provided has mentioned inspection date of 04-02-2020.*

2.	1.3.5	Evidence of approval of manufacturing facility/section approval from licensing authority shall be submitted.	GMP certificate has mentioned Tablet non antibiotic section. *However, no section approval letter is submitted.*
3.	3.2.S.4.1	Specification by the drug substance manufacturer has mentioned limit for residue on ignition of NMT 0.1% while the drug product manufacturer has mentioned NMT 0.5%. clarification shall be submitted.	Firm has submitted revised specifications for the drug substance wherein they have changed limits of residue on ignition from NMT 0.5% to NMT 0.1%. *Fee required for change in specification is not submitted.*
4.	3.2.S.4.2	Chromatographic conditions in the analytical method provided by the drug substance manufacturer i.e. λ max 275nm, column temperature 40 ˚C, injection volume 80µl, diluent composition (20:80) and mobile phase () are completely different from that provided by the drug product manufacturer i.e. λ max 223nm, column temperature 30 ˚C, injection volume 10µl, diluent composition (60:40) and mobile phase of acetonitrile and distilled water. Clarification shall be submitted.	Firm has submitted revised analytical method for drug substance as per parameters of the drug substance manufacturer. *No clarification is submitted.*
5.	3.2.S.4.3	Verification of analytical procedures performed by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.4	• Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance/Active Pharmaceutical Ingredient manufacture. • COA of the drug substance submitted by the finished product manufacturer has mentioned Shanghai YST pharma Co., Ltd., as manufacturer. Clarification shall be submitted.	Submitted. Firm has submitted new COA of the drug substance wherein they have mentioned Zhejiang Tianyu Pharma as manufacturer.
7.	3.2.S.7.3	Complete real time and accelerated stability studies for the three batches of the drug substance shall be submitted.	Firm has submitted new stability data sheets for the drug substance. Real time: 30˚C ± 2˚C / 65% ± 5% RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 06 months Batches: (13900-211201, 13900-211202 & 13900-211203)
8.	3.2.P.2.2	• Justification shall be submitted for not performing pharmaceutical equivalence studies and CDP against the innovator product. • Justification shall be submitted for performing only three tests in pharmaceutical equivalence studies.	Firm has submitted that CDP is performed against the brand leader. Firm has submitted revised pharmaceutical equivalence studies report with all the tests.

9.	3.2.P.5.2	Analytical procedure in dissolution test has mentioned rotation speed of 50rpm and time of 30 minutes while the review of the innovator product has mentioned 75rpm and 15 minutes' time. Justification shall be submitted.	Firm has submitted revised specifications as per innovator product i.e. 75rpm and 15 minutes' time in dissolution test.
10.	3.2.P.8	• Complete stability studies for batch No. EMP25-TR006 & EMP25-TR007 shall be submitted as only initial and 03rd month time point stability data for both accelerated as well as real time is submitted. • Justification shall be submitted for not performing content uniformity test in stability studies. • Analytical method for the assay test has mentioned to take 50mg of working standard and sample while the raw data sheets have mentioned 25mg of both. Clarification shall be submitted. • Documents for the procurement of API used in the development studies with approval from DRAP (in case of import) shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Submitted. Firm has submitted that content uniformity test is not a stability parameter. Firm has submitted revised stability reports wherein they have used 50 mg of sample and standard. *However, in the initially submitted data they used 25mg of both sample and standard.* Firm has submitted copy of commercial invoice No. YST19187A mentioning 450gm of Empagliflozin attested by Assistant Director I&E, DRAP, Lahore dated 14-02-2020. Copy of form 3 and Form 7 are also submitted. *No reply submitted.*

Decision: Approved. Registration letter will be issued after Submission Rs. 30,000/- for revision in most of the replies in the application and confirmation of GMP ststus.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

251.	**Name, address of Applicant / Marketing Authorization Holder**	**Werrick Pharmaceuticals, Plot No. 216-217, Sector I-10/3, Industrial Area, Islamabad.**
	Name, address of Manufacturing site.	Werrick Pharmaceuticals, Plot No. 216-217, Sector I-10/3, Industrial Area, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. F. 3-17/2018-Addl. Dir. (QA & LT-I)-52 dated 22-08-2022 issued on the basis of inspection conducted on 12-08-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter No. F. 1-41/92-Lic (Vol-II) dated 17-01-2019 wherein Table Section (General) is mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales.
	Dy. No. and date of submission	Form-5F Dy. No. 24499 dated 30-08-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 083424134 dated 26-08-2022.
	The proposed proprietary name / brand name	**Wardy plus XR Tablets 5mg/1000mg.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release film coated tablet contains; Empagliflozin …….…. 5mg Metformin Hydrochloride (extended release) ……. 1000mg
	Pharmaceutical form of applied drug	Extended release tablet.
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs. (A10BD20)
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	10's, 14's, 20's, 28's & 30's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Synjardy XR Tablets 5mg/ 1000 mg, USFDA approved.
	For generic drugs (me-too status)	Erli plus XR 5/1000mg tablets, PharmEvo, Reg. No. 105273.
	Name and address of API manufacturer.	**Metformin hydrochloride.** Abhilasha Pharma Pvt. Limited 1408, 1409, GID, EST. Anklishwar, 393002, Gujrat state India. GMP Certificate No: 19081546 valid up to 25/08/2022 issued by Food & Drugs Control Administration of Gujarat State, India. **Empagliflozin:** Kaifeng Pharmaceutical (Group) Company Limited. China Address: No.1, Yunan Street, Kaifeng, Henan Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Metformin HCl:** The firm submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for related substances, specifications, analytical procedures and its validation, batch analyses (MET065/19, mfg. date 01-05-2019) and justification of specification, reference standard, container closure system and stability studies of drug substance **Empagliflozin:** The firm submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers,

		description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analyses (HF180721, mfg. date 21-07-2018) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions and batches: **Metformin HCl.** Real time: 30˚C ± 2˚C / 65% ± 5% RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months Batches: (MET099/13, MET100/13 & MET101/13) **Empagliflozin:** Real time: 30˚C ± 2˚C / 65% ± 5% RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months Batches: (180205, 180227 & 180325)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, pharmaceutical development, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Brand i.e. Erli plus XR tablets 5/1000mg manufactured by M/s PharmEvo Karachi by performing quality tests (Identification, Tablet hardness, Assay, and Dissolution). CDP is also performed against the same brand that is Erli plus XR tablets 5/1000mg, Batch No. OL157, mfg. date 10-2020 & Exp. date 10-2022 manufactured by M/s PharmEvo Karachi in Acid media (0.1N HCl), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Method validation studies have been submitted including: system suitability, accuracy, and precision.

STABILITY STUDY DATA	
Manufacturer of API	**Metformin hydrochloride.** Abhilasha Pharma Pvt. Limited 1408, 1409, GID, EST. Anklishwar, 393002, Gujrat state India. GMP Certificate No: 19081546 valid up to 25/08/2022 issued by Food & Drugs Control Administration of Gujarat State, India. **Empagliflozin:** Kaifeng Pharmaceutical (Group) Company Limited. China Address: No.1, Yunan Street, Kaifeng, Henan Province, China.
API Lot No.	MET065/19 (Metformin HCl) HF180721 (Empagliflozin)
Description of Pack (Container closure system)	Alu-Alu blister pack 7's, 10's, 14's, 20's, 28's & 30's.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0,3, 6 (Months)

	Real Time: 0, 3, 6 (Months)		
Batch No.	TRIAL # 01	TRIAL # 02	TRIAL # 03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	24-04-2020	27-04-2020	28-04-2020
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Xetine 10mg tablets which was conducted on 03-03-2020 and was presented in 294th meeting of Registration Board held on 09th April, 2020. Registration Board decided to approve registration of Xetine Tablets 10mg and Xetine Tablets 20mg with innovator's specification
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Metformin hydrochloride.** Copy of GMP certificate No. 22093509 dated 29-08-2022 issued on the basis of inspection conducted on 02-03/08/2022 by Food & Drugs Control Administration, Gujrat State, India valid till 28-08-2025 is submitted. **Empagliflozin:** Copy of GMP certificate No. HA20190069 dated 29-09-2019 issued by He Nan Province Drug Administration valid till 28-09-2024 is submitted. They also submitted copy of DML No. YU 20150031 valid till 31-12-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of clearance certificate No. 2326 mentioning 01kg of Empagliflozin with B. No. HF180721 attested by Assistant Director I&E, DRAP, Islamabad. Firm has also submitted copy of commercial Invoice No: CIN20180726G02 dated Jul. 26, 2018, with 1kg quantity of Empagliflozin B. No. HF180721 attested by Assistant Director I&E, DRAP, Islamabad. **Metformin HCl:** Firm has submitted Export Invoice No. Exp013/2019-20 dated 05-06-2019 mentioning Metformin HCl, B. No. MET065/19 with quantity of 300kg attested by Assistant Director I & E, DRAP, Islamabad dated 01-07-19.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

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

Remarks OF Evaluator:

Sr. No.	Section No.	Observation	Response by the firm
1.	1.2	Table content from module 1 to module 5 shall be submitted.	Submitted.
2.	3.2.S.4.1	Justification shall be submitted for the analytical procedures of metformin HCl wherein assay test is titration based while the USP monograph of the drug substance has mentioned HPLC method.	Firm has submitted that they have adopted analytical procedures of Metformin HCl by titration base upon BP specifications. They also submitted COA of the drug substance from drug substance manufacturer wherein BP specifications are mentioned.
3.	3.2.P.2.2.1	• Justification shall be submitted for not performing PE and CDP against the innovator product. • Values of F2 shall be submitted for CDP results.	Firm has submitted Reference product i.e. Synjardy XR tablets manufactured by M/s Boehringer Ingelheim, USA are unavailable in Pakistan and even after their exhaustive efforts, they were unable to legally obtain the Reference product from abroad due to which CDP has not been performed against the innovator product. Furthermore, they have performed CDP & PE against me too product Erli Plus XR tablets manufactured by PharmEvo, Pakistan. Submitted.
4.	3.2.P.5.1	• Dissolution specifications for Empagliflozin has not mentioned specified time. Justification shall be submitted.	Firm has submitted that dissolution specifications for Empagliflozin has been adopted from innovator product i.e. NLT 80% Q in 45 minutes.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

252.	Name, address of Applicant / Marketing Authorization Holder	**M/s Asian Continental (Pvt.) Ltd., Continental House, D-133, Tipu Sultan Road, KDA Scheme-1, Karachi.**
	Name, address of Manufacturing site.	M/s Asian Continental (Pvt.) Ltd., D/32, S.I.T.E. Super Highway, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 07/2021-DRAP (K) dated 09-03-2021 issued on the basis of inspection conducted on 04th & 08th February, 2021 is submitted.

	Evidence of approval of manufacturing facility	Copy of letter No. F. 1-7/2002-Lic (Vol-I) dated 29-12-2008 mentioning Liquid ampoule (General) section is submitted by the firm.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25528; dated 09-09-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 18620117778 dated 24-06-2022.
	The proposed proprietary name / brand name	**JYSK 100mg/2ml Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains: Tramadol Hydrochloride …….. 100mg
	Pharmacotherapeutic Group of (API)	Opioid analgesic.
	Pharmaceutical form of applied drug	Clear colorless solution.
	Reference to Finished product specifications	Manufacturer/ACPL Specifications.
	Proposed Pack size	2ml x 5's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	ZYDOL 50 mg/ ml Solution for Injection, MHRA approved. (Each ZYDOL Solution for Injection ampoule contains 100mg tramadol hydrochloride in 2ml colorless aqueous solution.)
	For generic drugs (me-too status)	Tonoflex Injection 100mg/2ml ampoule by M/s Sami Pharmaceuticals, Karachi, Reg. No. 053224.
	Name and address of API manufacturer.	M/s. Proto Chemicals AG, (Grunenthal GmbH Quality Control) Tschachen 2, CH-8756 Mitloedi (Glarus-Sued) Switzerland.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance related to its nomenclature, structure, general properties,

		solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. S7137, Mfg. date 26-01-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{O} \pm 2^{O}$ C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{O}C ± 2^{O} C / 75% ± 5% RH for 60 months. (Batch No. E5846, E5861 & E5862)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description and composition, pharmaceutical development, manufacturer, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure, verification of analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalence against the product Tramal 100mg/2ml injection, B. No. C0030B, Mfg. date 06, 2021 manufactured by M/s Searle company limited by performing quality tests (Description, Identification, pH, Assay and volume variation).
	Analytical method validation/verification of product	Method validation studies have submitted including system suitability, specificity, linearity, range, accuracy & precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Proto Chemicals AG, (Grunenthal GmbH Quality Control) Tschachen 2, CH-8756 Mitloedi (Glarus-Sued) Switzerland.		
API Lot No.	S7137.		
Description of Pack (Container closure system)	Clear, colorless to yellowish solution filled in glass ampoules 1ml USP type I.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21PD-086	21PD-055	21PD-085
Batch Size	2500 ampoules	2500 ampoules	2500 ampoules
Manufacturing Date	10-2021	08-2021	10-2021
Date of Initiation	04-11-2021	02-09-2021	04-11-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 dated 04-03-2020 mentioning 1kg of Tramadol HCl USP attested by Assistant Director I&E, DRAP, Karachi dated 04-03-2020. Firm has also submitted proforma invoice No. TL-20/00003 dated 11-02-2020 mentioning 1kg of Tramadol HCl, Batch No. APL0040619 attested by Assistant Director I&E, DRAP, Karachi dated 04-03-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr. No.	Section Number	Observations	Firm's Response
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/ concerned regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate issued by Swissmedic in the name of M/s. Proto Chemicals AG, Glarus Sud. Certificate has mentioned that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on 10-03-2022. *However, no validity is mentioned on the certificate.*
2.	1.5.1 to 1.5.9	Detailed information of section 1.5.1 to 1.5.9 shall be submitted.	Submitted.
3.	3.2.S.4.1	Justification shall be submitted for providing Ph. Eur. specifications for the drug substance while the drug substance imported is of USP grade.	Firm has submitted that mistakenly they have submitted imported documents of M/s Aurabendo Pharma while their selected source is Proto Chemical AG Switzerland and they follow Ph. Eur. specifications Firm has also submitted revised form 6 No. 1324/2021 (K) dated 19-04-2021 mentioning 03Kg of Tramadol HCl Ph. Eur. Form 6 is attested by Assistant Director, DRAP, Karachi. Firm has also submitted proforma invoice No. CS-21/00231 dated 08-04-2021 mentioning Tramadol HCl, B. No. S7137, mfg. date of 26-01-2021. *However, invoice is not attested by DRAP.*

4.	3.2.S.4.3	Method verification studies performed by the drug product manufacturer shall be submitted.	Submitted.
5.	3.2.P.2.2	Justification shall be submitted for not performing particulate matter, Sterility and Bacterial endotoxin test in pharmaceutical equivalence studies.	Firm has submitted revised pharmaceutical equivalence studies wherein they have performed particulate matter, and endotoxin tests. They also submitted that for completion of sterility test, at least 14 days are required. After completion of sterility test they will also submit the results of the same.
6.	3.2.P.3	Justification shall be submitted for not performing the terminal sterilization of the applied formulation.	Firm has submitted that to ensure patient safety, parenteral drug products must be sterilized to destroy any potential microbial contamination. In manufacturing process they have mentioned that after filling process the trial batches of JYSK injection was proceeded for terminal sterilization at temperature of 121°C ± 1°C and pressure 100 kpa for 15 minutes.
7.	3.2.P.8	• API lot number mentioned in stability data sheets (57137) is different from that provided in 3.2.S.4.4 batch analysis. Justification shall be submitted. • Justification shall be submitted for not performing particulate matter, Sterility and Bacterial endotoxin test in stability studies of the drug product.	Firm has submitted that it was typographical error and actual lot No. is S7137. They also submitted revised data sheets with correct API lot number. Firm has submitted that these test were performed at initial time point and last time point. Initial results are recorded and already submitted in dossier in batch analysis. They also submitted revised stability data sheets wherein they have included the results of these tests.

Decision: Approved. Registration letter will be issued after Submission Rs. 7500/- for typo errors in the application.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

253.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 46/2021-DRAP (K) dated 07-10-2021 on the basis of inspection conducted on 15-06-2021 is submitted.
	Evidence of approval of manufacturing facility	Oral Liquid (General), Dry Powder suspension (General) Section approved vide letter No. F. 2-12/93-Lic (Vol-V) dated 20-09-2021 is submitted.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25617 dated 12-09-2022.
	Details of fee submitted	PKR 75,000/- vide slip No. 61669339268 Dated 30-08-2022.
	The proposed proprietary name / brand name	**Cloprex Suspension 50mg/ml.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Clozapine …… 50mg.
	Pharmacotherapeutic Group of (API)	Antipsychotic drugs (N05A).
	Pharmaceutical form of applied drug	Oral Suspension.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	30ml, 60ml, 100ml & 120ml.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	VERSACLOZ 50mg/ml (clozapine) oral suspension, USFDA approved.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s Shouguang Fukang Pharmaceutical Co., Ltd., North East of Dongwaihuan Road Dongcheng Industrial Area, Shouguang City, Shandong Province, China. Copy of GMP certificate No. SD20190888 dated 13-03-2019 issued by Shandong Food and Drug Administration valid till 12-03-2024 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted summarized information for both the drug substances related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. A-51012102002, mfg. date 16-02-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months Real time: 30˚C ± 2˚C/65% ± 5%RH for 60 months. Batches: (200911004, 200911005 & 200911006)
	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 drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator product i.e. Versacloz oral suspension 50mg/ml, B. No. 8015.007AA manufactured by Tasman Pharma by performing quality test of appearance, identification, pH &, assay. Results of both the test product and reference product are within the specifications limit and comparable. ***However, Specifications are not a per BP monograph for the applied formulation.***
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Shouguang Fukang Pharmaceutical Co., Ltd., North East of Dongwaihuan Road Dongcheng Industrial Area, Shouguang City, Shandong Province, China.		
API Lot No.	RM-6127.		
Description of Pack (Container closure system)	Yellow colour suspension filled in Amber PET Bottle packed with syringe dropper and leaf insert.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21SB(B)-067-01	21SB(B)-068-02	21SB(B)-069-03
Batch Size	2250 ml	2250 ml	2250 ml
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	20-09-2021	20-09-2021	20-09-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SD20190888 dated 13-03-2019 issued by Shandong Food and Drug Administration valid till 12-03-2024 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. 21VIT-439 dated 22-06-2021 specifying 25 Kg of Clozapine USP, B. No. A-51012102002, mfg. date 16-02-2021. The invoice is cleared by Assistant Director, DRAP, Karachi dated 29-06-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.

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

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.6	This section has mentioned innovator's specification while the official monograph for clozapine suspension is available in BP. Clarification shall be submitted.	Firm has submitted that since their API specifications are USP specifications, while the product monograph is not available in USP, so that's why they claimed innovator specifications. *Official monograph for clozapine suspension is available in BP.*
2.	3.2.S.4.2	Composition of the mobile phase in the submitted analytical method for assay test is different from both USP and that of the drug substance manufacturer in respect of trimethylamine. Justification shall be submitted.	Firm has submitted that analytical method from drug substance and drug product manufacturer is same as per USP method. Quantity of trimethylamine is 0.75ml for 1000ml or one liter.
3.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.5	Details/COA of the working standard used in the development studies shall be submitted.	Submitted.
5.	3.2.P.2.2	• Justification shall be submitted for adopting different specifications for assay & pH tests than BP monograph. • Justification shall be submitted for not performing content uniformity test and microbial count test on the finished product. • Pictorial evidence of the innovator product with visible details of batch number, manufacturing date etc. shall be submitted.	Firm has submitted that they follow innovator's specification for pH i.e. 6.5 to 7.0. The active component of versacloz is clozapine. The remaining components are glycerine, sorbitol (crystallizing), sodium dihydrogen phosphate dihydrate, xanthan gum, sodium methyl paraben, sodium propyl paraben, povidone, water and sodium hydroxide to adjust to a pH range of 6.5 – 7.0. *pH limit in BP monograph for clozapine oral suspension is 4.0 – 6.0 while the applied formulation has mentioned 6.5 to 7.0.* *Similarly Assay limit are 95% - 105% in BP monograph while the applied formulation has mentioned 90% - 110%.* *Innovator's data has not revealed any pH limit for the same formulation.* Firm has submitted that as per USP General Chapter <905> CU test is not applicable for multiple dose containers however; we have performed microbial count test on finished product. They also submitted the results of microbial count test. Firm has provided pictorial evidence of the innovator product, lot No. 8015.007A, Exp. Date 04/22.
6.	3.2.P.5.1	Justification shall be submitted for not following the BP specifications for applied formulation for pH and assay test.	Firm has submitted that as per their stability data they concluded that all assay results lie between 95% - 105% so we revise our assay

		pH limit in BP is 4.0 to 6.0 while the specification submitted are 6.5 to 7.0. Assay limits in BP are 95.0% to 105.0% while the specification submitted are 90.0% to 110%.	specifications as per BP. They also submitted revised assay limits/specifications. *Fee for revision of specifications shall be submitted.* *However, no justification is submitted for pH limits of the applied formulation.*
7.	3.2.P.5.2	Justification for difference in the analytical methods from BP monograph shall be submitted.	Firm has submitted that they used raw material testing as per USP specifications and same was applied on finished product testing because the finished product monograph was not published in USP. They further added that BP monograph was not followed because API specification was on USP specifications.

Decision: Approved with BP Specifications. Registration letter will be issued after Submission Rs. 7500/- for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

254.	Name, address of Applicant / Marketing Authorization Holder	**M/s Barrett Hodgson Pakistan (Pvt.) Ltd., F/423, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	M/s Barrett Hodgson Pakistan (Pvt.) Ltd., F/423, S.I.T.E., Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 007/2022-DRAP (K) dated 20-01-2022 issued on the basis of inspection conducted on 06-12-2021 is submitted.
	Evidence of approval of manufacturing facility	Copy of letter No. F. 2-4/97-Lic (Vol-IV) dated 23-12-2021 mentioning Sterile Liquid injection SVP (General - New section is submitted by the firm.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26102; dated 14-09-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 711958440 dated 17-08-2022.
	The proposed proprietary name / brand name	**Ketobar 30mg/ml Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ketorolac Tromethamine …….. 30mg
	Pharmacotherapeutic Group of (API)	NSAID
	Pharmaceutical form of applied drug	Clear, colorless to yellowish solution filled in glass ampoules 1ml USP type I.
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1ml x 5's.

	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	US FDA approved.
	For generic drugs (me-too status)	Tekac 30mg/ml Injection, Sami Pharmaceuticals, Reg. No. 092855.
	Name and address of API manufacturer.	M/s. Saurav Chemicals Limited 370 Industrial Area, Phase II Panchkula, Haryana, 134109 – India. **Manufacturing site address:** M/s. Saurav Chemicals Limited, Derabassi – Barwala Road, Village Bhagwanpura, Tehsil Derabassi, District Sahibzada Ajit Singh Nagar (Punjab) India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. KTM190017, Mfg. date 09-2019) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{O} \pm 2^{O}$ C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{O}C ± 2^{O} C / 65% ± 5% RH for 60 months. (Batch No. KTM06150007, KTM06150008 & KTM06150009)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description and composition, pharmaceutical development, manufacturer, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure, verification of analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug

		product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalence against the product Toradol injection 30mg, B. No. C5290, Mfg. date 11, 2020 by performing quality tests (Description, Identification, pH, Assay, particulate matter, Sterility and Bacterial endotoxin).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Saurav Chemicals Limited 370 Industrial Area, Phase II Panchkula, Haryana, 134109 – India. **Manufacturing site address:** M/s. Saurav Chemicals Limited, Derabassi – Barwala Road, Village Bhagwanpura, Tehsil Derabassi, District Sahibzada Ajit Singh Nagar (Punjab) India.		
API Lot No.	KTM1900017.		
Description of Pack (Container closure system)	Clear, colorless to yellowish solution filled in glass ampoules 1ml USP type I.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EXP-I-183	PLT-I-013	PLT-I-014
Batch Size	1000 ml	1500 ml	1500 ml
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	12-2021	01-2022	01-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. Drugs (3) Pb. 2021/3124 dated 25-06-2021 for M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India issued by Food & Drugs Administration, Punjab is submitted by the firm. GMP certificate is valid till 25-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. SCL/2021-22/210 dated 22-10-2021 mentioning 0.3kg of ketorolac Tromethamine USP with B. No. KTM190017, mfg. date 01-09-2019 attested by Assistant Director I&E, DRAP, Karachi dated 03-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.

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

Remarks of Evaluator:

Sr. No.	Section Number	Observations	Firm's Response
1.	1.6.5	Valid GMP certificate of API manufacturer issued by regulatory body of country shall be submitted.	Firm has submitted copy of GMP certificate No. Drugs (1) Pb. 2023/5235 dated 03-07-2023 for M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Village Bhagwanpura, Tehsil Derabassi, District Sahibzada Ajit Singh Nagar (Punjab) India issued by Food & Drugs Administration, Punjab valid till 13-09-2024.
2.	2.3	Table for literature references has mentioned only USP for drug substance. Revised table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	Firm has submitted revised table for literature references with correct information with submission of 7500/- fee vide slip No. 89846074681 dated 11-01-2024.
3.	3.2. P.3.3	Flow diagram for the manufacturing process and description of manufacturing process has mentioned terminal sterilization of the applied formulation. Scientific justification shall be submitted for performing terminal sterilization of the applied formulation.	Firm has submitted that Ketobar Injection 30mg/ml having same quantitative and qualitative composition as per innovator's product Toradol Injection 30mg/ml. It contains Ethanol 96% (v/v) as an ingredient and its concentration in finished product is only 10%. They further submitted that Innovator's product Toradol Injection 30mg/ml was being manufactured at Barrett Hodgson Pakistan for 10 years (from 2011 till cancellation of registration in 2021). Its registration was transferred from Martin Dow to local manufacturing at Barrett Hodgson Pakistan in 15th June 2011 later it was transferred back to Martin Dow for manufacturing at their site in 2021, 297th DRB. Toradol Injection 30mg/ml was being manufacturing in past at Barre.tt Hodgson Pakistan as per Roche standard and they have recommended for terminal sterilization This recommendation is also supported by regulatory bodies in the United States (US) and European Union (EU) that terminal sterilization is preferred and should be considered first to minimize the risk of contamination and its consequences.

Decision: Registration Board after thorough deliberation and keeping in view the contract manufacturing of the same product for innovator, decided to approve the product

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
255.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Venus Pharma, 23-Km, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Venus Pharma, 23-Km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 353/2019-DRAP (AD-1915187-536) dated 28-11-2019 issued on the basis of inspection conducted on 05-09-2019.
	Evidence of approval of manufacturing facility	Not submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales.
	Dy. No. and date of submission	Form-5F Dy. No. 27750 dated 30-09-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 655622716 dated 31-05-2022.
	The proposed proprietary name / brand name	**Valron Emulgel 2%.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100gm contains; Diclofenac Diethyl ammonium salt 2.32.gm eq. to Diclofenac sodium ……. 2gm.
	Pharmaceutical form of applied drug	Topical gel.
	Pharmacotherapeutic Group of (API)	NSAID.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	1 x 1's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Voltarol 12 hours Emulgel 2.32%, MHRA approved.
	For generic drugs (me-too status)	Voltral Emulgel 2%, GSK OTC (Pvt.) Ltd., Reg. No. 089372.
	Name and address of API manufacturer.	M/s Srikem Laboratories (Pvt.) Ltd., Plot No. 17/24, M.I.D.C. Taloja- 410 208, Navi, Mumbai, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of

		drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analyses (185008003, mfg. date 06-2018) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions and batches: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 06 months Batches: (195008001, 205008002 & 175008002).
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, pharmaceutical development, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Brand i.e. Voltral Emulgel 2%, GSK OTC (Pvt.) Ltd., by performing quality tests (Disintegration, Identification, Average weight and Assay).
	Analytical method validation/verification of product	Method validation studies have been submitted including: Accuracy, precision, linearity and specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Srikem Laboratories (Pvt.) Ltd., Plot No. 17/24, M.I.D.C. Taloja- 410 208, Navi, Mumbai, India.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Printed and sealed Alu-Alu tubes having plastic cap further packed in board unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0,3, 6 (Months) Real Time: 0, 3, 6, 9 (Months)		
Batch No.	19	20	
Batch Size	500 Tubes	500 Tubes	
Manufacturing Date	09-2021	09-2021	
Date of Initiation	11-09-2021	11-09-2021	
No. of Batches	02		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section No.	Observation	Response by the firm
1.	1.3.4	• Valid copy of DML of the applicant shall be submitted as the provided one is w.e.f. 25-12-2015. • Valid copy of GMP certificate/last inspection report conducted within last three years shall be submitted.	Firm has once again submitted the same DML w.e.f. 25-12-2015. *Valid DML is required.* Copy of GMP certificate No. 04/2024-DRAP(AD-46168323) dated 02-01-2024 issued on the basis of inspection conducted on 22-08-2023 & 14-09-2023.
2.	1.3.5	Evidence of approval of manufacturing facility/section approval from licensing authority shall be submitted.	Above mentioned GMP certificate has mentioned cream/ointment section.
3.	1.5.2	This section has mentioned that each 100gm contain Diclofenac Diethyl ammonium salt eq. to 2.32.gm of Diclofenac sodium. Clarification shall be submitted.	Firm has submitted that their product composition is 2% and factor is adjusted according to molecular weight of Diclofenac diethyl ammonium salt. *Firm was asked that they have written Diclofenac Diethyl ammonium salt eq. to 2.32.gm of Diclofenac sodium which is incorrect and 2.32% in label claim. However, they didn't answer the same.*
4.	3.2.S.4.1	Specification of the drug substance from drug substance manufacturer shall be submitted.	Submitted.
5.	3.2.S.4.2	Analytical procedures of the drug substance from drug substance manufacturer shall be submitted.	*Not submitted.*

6.	3.2.S.4.3	Verification of analytical procedures of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
7.	3.2.S.4.5	Details/COA of the working standard used shall be submitted.	Firm has submitted copy of COA of working standard for diclofenac sodium. *However, COA is from M/s Henen Dongtai Pharm Co., Ltd.*
8.	3.2.S.7.3	Accelerated stability studies for the three same batches for which real time stability studies are submitted shall be provided. OR Real time and accelerated stability data for the same batches as per zone Iva shall be submitted.	Firm has once again submitted the same stability data. *Real time and accelerated stability batches are not the same.*
9.	3.2.P.5.1	Justification shall be submitted for not including content uniformity, pH and microbial studies in the specifications of the drug product.	Firm has submitted that content uniformity is applied on single/metered dose containers according to general monographs of topical semi solid preparation in B.P. Firm further submitted that both pH & microbial studies are not included in that monograph.
10.	3.2.P.5.3	Analytical method verification protocol along with analytical method verification studies performed on the finished product shall be submitted.	Submitted.
11.	3.2.P.5.4	Justification shall be submitted for developing only two trial batches.	Firm has submitted that as per guidance document of Form 5F; (a) At least 2 batches having the following minimum batch size considering the scientific reliability • OSDs: 5000 Units • Oral Liquid/Suspension: 2000 • Injectable: 2000 • Aerosol and any other specialized preparations: 500 (b) At least 3 batches having scientifically rational batch size, sufficient enough to perform complete testing till the claimed shelf life. *From the above statement of the guidelines, 02 batches with 500 units are for Aerosol and any other specialized preparations while as per point "b" At least 3 batches having scientifically rational batch size, sufficient enough to perform complete testing till the claimed shelf life shall be manufactured. However, firm has manufactured only two trial batches with 500 units.*
12.	3.2.P.8	• Justification shall be submitted for not performing content uniformity test and	Firm has submitted that content uniformity is applied on single/metered dose containers according to general

		pH and microbial test in stability studies.	monographs of topical semi solid preparation in B.P. Firm further submitted that both pH & microbial studies are not included in that monograph. *Not submitted.*
		• Stability data sheets as per decision of Registration Board with inclusion of API lot number shall be submitted.	*Firm has also submitted raw data sheets wherein the final concentration used by the FPP is 0.02mg/ml while BP monograph has mentioned 0.05/ml.*
		• Approval of API/ DML/GMP certificate (valid) of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 6077473dated 07-09-2017 issued by Food & Drugs Administration Maharashtra State, India in the name of M/s Srikem Laboratories (Pvt.) Ltd., valid till 06-09-2018. *Valid copy of GMP certificate is required.*
		• Documents for the procurement of API used in the development studies with approval from DRAP (in case of import) shall be submitted.	Firm has submitted copy of invoice No. E-1819136 dated 20-10-2018 mentioning 25 kg of diclofenac diethyl amine BP, B. No. 185008003, mfg. date 06-2018 attested by Assistant Director, DRAP, Lahore dated 26-10-2018.
		•	Not applicable.
		• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	

Decision: Deferred for following;

- **Valid copy of DML of the applicant shall be submitted.**
- **Revision of label with submission of full fee as per reference product.**
- **Analytical procedures of the drug substance from drug substance manufacturer shall be submitted.**
- **Real time and accelerated stability data of the drug substance for the same batches as per zone Iva shall be submitted.**
- **Justification shall be submitted for using final concentration of 0.02mg/ml in the submitted raw data sheets while BP monograph has mentioned 0.05/ml.**
- **Approval of API/ DML/GMP certificate (valid) of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.**

256.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. F.11-95/19-DRAP-64 dated 14-10-2019 issued on the basis of inspection conducted on 27-09-2019 is submitted. ***Both DML and GMP certificate are not valid.***
	Evidence of approval of manufacturing facility	Not submitted.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27751 dated 21-09-2022.
	Details of fee submitted	PKR 30,000/-, vide slip No. 0243315222 Dated 01/08/2022.
	The proposed proprietary name / brand name	**Ten-Alfa 25mg tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tenofovir Alafenamide as Fumarate ……25mg
	Pharmacotherapeutic Group of (API)	Nucleoside and Nucleotide Reverse Transcriptase Inhibitors (J05AF).
	Pharmaceutical form of applied drug	Oral tablet.
	Reference to Finished product specifications	In-house Specifications.
	Proposed Pack size	3 x 10's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Vemlidy 25 mg film-coated tablets MHRA approved.
	For generic drugs (me-too status)	Tefod 25mg tablets, Sami Pharmaceuticals, Reg. No. 096182.
	Name and address of API manufacturer.	M/s Jinan Xinke Pharmaceutical Sci. & Tech. Co., Ltd., Room 403, Building A, No. 474 Zhengfeng Road, Gaoxin Kaifa District, Jinan, Shandong Province, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted details of the drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (B. No. 19090401, mfg. date 09-2019) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. Batch No. (2018082801, 2018082901 & 2018083001)

	Module-III Drug Product:	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence is not provided by the applicant. CDP has been performed against the brand that is Tenofomide 25mg tablets, B. No. 004FB1, mfg. date 04-2020 manufactured by M/s Getz pharma in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). More than 85% release in all the three mediums.
	Analytical method validation/verification of product	Not Submitted.

STABILITY STUDY DATA

Manufacturer of API			
API Lot No.	19090401.		
Description of Pack (Container closure system)	Alu Alu blister of 3 x 10's further packed in bleech card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-013	T-014	T-015
Batch Size	1200 Tablets.	1200 Tablets.	1200 Tablets.
Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	10-12-2019	10-12-2019	10-12-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm.
1.	1.3.4	Valid copy of DML and GMP certificate/last inspection report conducted within last three years of the applicant shall be submitted.	
2.	1.3.5	Evidence of approval of manufacturing facility/section approval from licensing division shall be submitted.	
3.	1.5.2	Section 1.5.2 has mentioned In-House Specification while 3.2.P.1 has mentioned Innovator's specifications for the drug product. Clarification shall be submitted in this regard.	
4.	1.5.15 to 1.5.20	Signed undertakings shall be submitted.	
5.	1.6.5	Section 1.6.5 has mentioned M/s Jinan Xinke Pharmaceutical Sci. & Tech. Co., Ltd., China as drug substance manufacturer while 2.3 and 3.2.S has mentioned M/s Shandong Sihuan Pharmaceutical Co., Ltd., as drug substance manufacturer. Clarification shall be submitted.	
6.	3.2.S.4.1	Specification of the drug substance from drug substance manufacturer shall be submitted.	
7.	3.2.S.4.2	Analytical procedures of the drug substance from both the drug substance and drug product manufacturer shall be submitted.	
8.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer along with method verification protocol shall be submitted.	
9.	3.2.S.4.4	• COA of the drug substance submitted by drug product manufacturer has different specifications than submitted by the drug product manufacturer in 3.2.S.4.1. Justification shall be submitted. • Justification shall be submitted for not performing most of the test in the COA submitted by drug product manufacturer. • COA of the drug substance submitted by drug product manufacturer has mentioned Shandong Haiyou Freda Pharma Co. Ltd., as manufacturer. Clarification shall be submitted. • COA of the drug substance from drug substance manufacturer with same batch number shall be submitted.	

10.	3.2.S.5	COA/details of the working standard shall be submitted.	
11.	3.2.S.7	Real time stability data of three batches for the drug substance from drug substance manufacturer as per zone Iva shall be submitted.	
12.	3.2.P.2.2	• Pharmaceutical equivalence studies of the applied formulation against the innovator product shall be submitted. • Justification shall be submitted for not performing CDP against the innovator product shall be submitted.	
13.	3.2.P.3.3	Description of manufacturing process shall be submitted.	
14.	3.2.P.5.1	Dissolution specifications of the applied formulation i.e. dissolution medium (0.1N HCl), volume (900), RPM (50) and time (30) minutes are different from the innovator product approved in USFDA i.e. Vimlidy dissolution medium (50mM sodium acetate buffer), volume (500), RPM (75) and time (15) minutes. Clarification shall be submitted.	
15.	3.2.P.5.2	Analytical procedures for all the tests of the finished product with details shall be submitted.	
16.	3.2.P.5.3	Complete validation studies along with method validation protocol shall be submitted.	
17.	3.2.P.8	• Justification shall be submitted for not performing content uniformity test in the stability studies. • Justify the concentration of standard preparation and sample preparation in the submitted chromatograms with respect to concentrations provided in the analytical procedure. As both are different from the analytical procedure. • Justification shall be submitted regarding the submitted chromatograms as chromatograms are for Alovir tablets. • Raw data sheets for calculation of assay and dissolution tests at each time point shall be submitted. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of	

		stability chambers (real time and accelerated) shall be submitted.	
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.			
257.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd., Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.**	
	Name, address of Manufacturing site.	M/s Hudson Pharma (Pvt.) Ltd., D-93, North West Industrial Zone, Port Qasim Authority, Karachi.	
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)	
	GMP status of the firm	**M/s Scilife Pharma:** Copy of GMP certificate No. 29/2021-DRAP (K) dated 17-06-2021 on the basis of inspection conducted on 01-03-2021 is submitted. **M/s Hudson Pharma:** Copy of GMP certificate No. 58/2022-DRAP (K) dated 04-04-2022 on the basis of inspection conducted on 07-10-2021 is submitted.	
	Evidence of approval of manufacturing facility	Plastic ampoule (BFS Technology) section is approved vide letter No. F. 2-12/2010-Lic dated 30-08-2016 in 248th meeting of Central licensing Board.	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales	
	Dy. No. and date of submission	Dy. No. 27448 dated 28-09-2022.	
	Details of fee submitted	PKR 75,000/- vide slip No. 75509339876 Dated 20-09-2022.	
	The proposed proprietary name / brand name	**Ipra-S 0.5/2.5 mg Inhalation Solution 2.5ml.**	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Ipratropium Bromide ……...…0.5mg Salbutamol Sulfate 3mg eq. to Salbutamol ..…2.5mg	
	Pharmacotherapeutic Group of (API)	R03A Adrenergic, Inhalants.	
	Pharmaceutical form of applied drug	Nebulizer solution.	
	Reference to Finished product specifications	USP specifications.	
	Proposed Pack size	5 x 2.5ml.	
	Proposed unit price	As per SRO.	
	The status in reference regulatory authorities	Combivent® UDVs® MHRA approved. Each 2.5 ml single dose unit contains 500 micrograms ipratropium bromide (as 520 micrograms ipratropium bromide monohydrate) and 3 mg salbutamol Sulfate (corresponds to 2.5mg salbutamol base).	
	For generic drugs (me-too status)	Combihale Respules, Hudson Pharma, Reg. No. 090971	

	Name and address of API manufacturer.	**Ipratropium Bromide:** Olon S.p.A, Via Livelli, 126852 Casaletto Lodigiano (Frazione Mariano), Italy. Copy of GMP certificate No. IT-API/4/H/2021 issued by AIFA, Italy on the basis of inspection conducted on 29-06-2018 valid for three years is submitted. **Salbutamol Sulfate:** M/s Cipla Limited, Plot Nos. A-2, A-33 & A-37/2/2, M.I.D.C., Patalganga, Raigad 410220 Maharashtra State, India. Copy of GMP certificate No. NEW-WHO-GMP/CERT/KD/107920/2022/11/39128 dated 17-02-2022 issued by Food and Drug Administration M.S. Bandra-Kurla Complex, Bandra(E), Mumbai valid till 16-02-2025 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted summarized information for both the drug substances related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of both the drug substance and drug product.
	Module-III Drug Substance:	**Ipratropium Bromide:** Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 1750000358, mfg. date 28-07-2017) and justification of specification, reference standard, container closure system and stability studies of drug substance. **Salbutamol Sulfate:** Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. HDP160180, mfg. date 11-2015) 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)	**Ipratropium Bromide:** Stability study conditions: Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (9800/03/04, 9800/01/05 & 9800/01/06) Real time: 30°C ± 2°C/65% ± 5%RH for 60 months. Batches: (9800/04/14, 9800/05/14 & 9800/06/14) **Salbutamol Sulfate:** Stability study conditions: Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (H40085, H40086 & H40087) Real time: 30°C ± 2°C/65% ± 5%RH for 36 months for two batches and 12 months for last batch.

		Batches: (H1000062, H110020 & H130073)
	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 drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator product i.e. Combivent, B. No. 2984201, mfg. date 01-2022 manufactured by Boehringer Ingelheim, Germany by performing quality test of appearance, identification, pH, Osmolality, assay & degradation product. Results of both the test product and reference product are within the specifications limit and comparable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	**<u>Ipratropium Bromide:</u>** Olon S.p.A, Via Livelli, 126852 Casaletto Lodigiano (Frazione Mariano), Italy. **<u>Salbutamol Sulfate:</u>** M/s Cipla Limited, Plot Nos. A-2, A-33 & A-37/2/2, M.I.D.C., Patalganga, Raigad 410220 Maharashtra State, India.		
API Lot No.	1750000358, HDP160180, 9800/0316.		
Description of Pack (Container closure system)	Inhalational solution packed in LDPE respules further wrapped in a foil and packed in unit cartons with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6, 9, 12, 18, 24 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	18J003	18J004	18J005
Batch Size	180L	180L	180L
Manufacturing Date	08-2018	08-2018	08-2018
Date of Initiation	05-09-2018	08-09-2018	24-09-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**<u>Ipratropium Bromide:</u>** Olon S.p.A, Via Livelli, 126852 Casaletto Lodigiano (Frazione Mariano), Italy. Copy of GMP certificate No. IT-API/4/H/2021 issued by AIFA, Italy on the basis of inspection conducted on 29-06-2018 valid for three years is submitted. **<u>Salbutamol Sulfate:</u>** M/s Cipla Limited, Plot Nos. A-2, A-33 & A-37/2/2,

		M.I.D.C., Patalganga, Raigad 410220 Maharashtra State, India. Copy of GMP certificate No. NEW-WHO-GMP/CERT/KD/107920/2022/11/39128 dated 17-02-2022 issued by Food and Drug Administration M.S. Bandra-Kurla Complex, Bandra(E), Mumbai valid till 16-02-2025 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ipratropium Bromide:** Firm has submitted copy of invoice No. 7000000306 dated 03-03-2017 mentioning 0,500 kg of Ipratropium Bromide, B. No. 9800/03/16. The invoice is cleared by Assistant Director, DRAP, Karachi dated 07-04-2017. **Salbutamol Sulfate:** Copy of commercial invoice No. CIP/EXP/006 dated 30-09-2016 mentioning 1200 gm of salbutamol Sulphate attested by Assistant Director, DRAP, Karachi dated 05-10-2016 is submitted by the firm. Firm has also submitted copy of Form 6 attested by Assistant Director, DRAP, Karachi dated 05-10-2016.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	This section has mentioned Ipratropium Bromide 500mcg while the reference product has mentioned 500 micrograms ipratropium bromide (as 520 micrograms ipratropium bromide monohydrate). Revision of label claim along with submission of applicable fee shall be submitted.	Firm has submitted revised label claim with submission of 7500/- fee vide slip no. 2589121038 dated 14-02-2024 and 67500/- vide slip No. 303201882 dated 08-03-2024. Revised label claim is as under; Each 2.5ml single dose unit Contains: Ipratropium Bromide ……..… 500mcg (As 520mcg Ipratropium Bromide monohydrate) Salbutamol Sulfate 3mg eq. to Salbutamol ..…2.5mg
2.	1.6.5	Valid copy of GMP certificate for ipratropium bromide issued by concerned/relevant regulatory authority shall be submitted.	Copy of GMP certificate No. IT-API/158/H/2023 issued by AIFA, Italy on the basis of inspection conducted on 04-03-2022 valid for three years is submitted.
3.	3.2.S.4.1	Specifications of the drug substance Ipratropium bromide provided by the drug product manufacturer are different for pH value than both USP and finished product manufacturer. Clarification shall be submitted.	Firm has submitted that drug product manufacturer is following BP monograph wherein pH limits are 5.0 – 7.5. while drug substance manufacturer shows pH limits of 5.0 – 7.0 which is narrowed & this makes the most stringent acceptance criteria.
4.	3.2.S.7	Real time stability studies and accelerated stability of both the drug substances for same batches shall be submitted.	Ipratropium Bromide: Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months.

			Real time: 30°C ± 2°C/65% ± 5%RH for 60 months. Batches: (9800/03/04, 9800/01/05 & 9800/01/06) Salbutamol Sulfate: Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months. Real time: 30°C ± 2°C/65% ± 5%RH for 60 months. Batches: (HDA160020, HDA160022 & HDA160027.
5.	3.2.P.2.2	• Justification shall be submitted for not performing uniformity of dosage unit, particulate matter and sterility tests in the pharmaceutical equivalence studies. • Pictorial evidence of the innovator product with visible information of batch number, manufacturing date and name of manufacturer shall be submitted. • Justification shall be submitted regarding the batch number and manufacturing date submitted in the pharmaceutical equivalence as the trial batches are manufactured in 08/2018 while the pharmaceutical equivalence studies have mentioned august 2022 for applied formulation and January 2022 for innovator product.	Firm has submitted revised PE studies wherein they have added uniformity of dosage unit, particulate matter and sterility tests. Firm has submitted picture of Combivent ®, B. No. 3984206, mfg. date 04-2023 & Exp. Date 03-2025 manufactured by Boehringer Ingelheim. *However, the manufacturing date and batch number etc. mentioned in the dossier are different from the submitted picture.* Firm has submitted that as confirmed by the manufacturer, trial batches were manufactured in 2018 and the dossier was applied in the same year. The pharmaceutical equivalence test was not applicable at that time. Furthermore, as per CTD guidelines, it is not mandatory to use the same batch for stability studies and PE studies.
6.	3.2.P.8	Justification shall be submitted for not performing Uniformity of dosage units test on the finished product.	Firm has submitted updated testing parameters including uniformity of dosage units in the finished product testing method.

Decision: Approved with following label claim:

Each 2.5ml single dose unit Contains:

Ipratropium Bromide ……..… 500mcg

(As 520mcg Ipratropium Bromide monohydrate)

Salbutamol Sulfate 3mg eq. to Salbutamol ..…2.5mg

Applicant shall submit PKR 7500/- pre-registration variation fee for revision of label claim, prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023 before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Agenda of Evaluator PEC-XV

Cases of Finished Import of Form 5-F:

258.	Name, address of Applicant / Importer	M/s: Sohail Corporation Address: Plot no 7, SR-5, Serai Quarters, Techno City Ware house no 42, Karachi-Pakistan.
	Details of Drug Sale License of	License No: 239

	importer	Address: Plot no 7, SR-5, Serai Quarters, Techno City Ware house no 42, Karachi-Pakistan. Address of Godown: NA Validity: 18-Nov-2027 Status: Stock, Exhibit to sell, License to sell drugs as distributor by way of wholesale Renewal: Our license has been renewed and the details written above are for the renewed licenses.
	Name and address of marketing authorization holder (abroad)	M/s.Tianjin King York Group Hubei Tianyao Pharmaceuticals Co. Ltd. No.99 Hanjiang Bei Road, Xiangyang, Hubei, P.R. China.
	Name, address of manufacturer(s)	Name of Manufacturer: M/s.Tianjin King York Group Hubei Tianyao Pharmaceuticals Co. Ltd. Address: No.99 Hanjiang Bei Road, Xiangyang, Hubei, P.R. China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized CoPP certificate No:20211201 Dated 09-02-2022 issued by Hubei Xiangyang Administration for Market Regulation of the Peoples Republic of China No.41.Chunyuan Road, Xiangyang City, Hubei Province. and validity is for two years. Firm has submitted GMP certificate no.HB20190552 of Manufacturer M/s.Tianjin KingYork Group Hubei Tianyao Pharmaceuticals Co. Ltd. No.99, HanjiangBei Road, XiangYang City, Hubei Province and the certificate remain valid until; 26-11-2024.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of agent & distributor agreement dated 18th June,2021 between three companies. The letter species that the M/s. Qingdao JidaBarr International Trade Co. Ltd., China is the Exporter, M/s. Sohail Corporation Karachi is the Distributor and M/s. Tianjin KingYork KingDroy International Trading Co. Ltd. a company incorporated in China having its registered Unit 1702, Yangzhao Building, Tianjin Pilot Free Trade Zone, Tianjin China hereby on behalf of Tianjin KingYork Group Hubei Tianyao Pharmaceuticals Co. Ltd. No.99, HanjiangBei Road, XiangYang City, Hubei Province is the Manufacturer. The Manufacturer is engaged in manufacturing and desired to enter into an agreement with the exporter to export these products to the Pakistan Territory.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only

	Dy. No. and date of submission	Dy.no. 27734 dated 20-09-2022
	Details of fee submitted	PKR 150,000/-: vide slip no. 7062718500 dated 23-09-2022.
	The proposed proprietary name / brand name	**Paracetamol Injection 1g/100ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml solution contains……1g
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Analgesic and Antipyretic
	Reference to Finished product specifications	In-house
	Proposed Pack size	1 bottle of 100ml packed in printed unit box with a product leaflet
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (Acetaminophen 1g/100ml)
	For generic drugs (me-too status)	Parazyl L Injection of M/s. Searle IV solution Pvt. Ltd., Lahore (Reg.no. 078617)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. Anqiu Lu'an Pharmaceuticals Co. Ltd. No.35 Weixu North Road, Aniqu, Shandog, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 30ºC ± 2ºC and 75%+5 RH. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and	Firm has submitted Pharmaceutical Equivalence studies report

	Comparative Dissolution Profile	against the reference product of M/s. Cisen Pharmaceuticals Co. Ltd., China (Paracetamol Injection 1g/100ml), but an incomplete report has been submitted by the firm.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	100ml type I glass bottle made of low borosilicate glass: Butyl rubber stopper.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH. The real time stability study data of 3 batches is for 36 months

Evaluation by PEC:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.3	Provide analytical method validation report performed by drug product manufacturer.
2.	3.2.S.4.4	Provide batch analysis report of drug substance by the drug product manufacturer.
3.	3.2.S.5	Provide certificate of analysis of reference standard /working standard used for testing of the product.
4.	3.2.P.2.2.1	Submitted equivalence report did not include the results of applied product of Tianjin KingYork Group Hubei Tianyao Pharmaceutical Co. Ltd. along with quality analysis reports of reference product. Submit the comparison/equivalence report mentioning the quality results of both test and reference product.
5.	3.2.P.5.1	Justify for keeping the pH of drug product between 4.5-6.0 when the innovator recommends pH between 5.0 and 6.3.
6.	3.2.P.5.4	Assay procedure given in section 3.2.P.5.2 is different from the assay method validated in section 3.2.P.5.4, justification is required in this regard.
7.	3.2.P.7	Clarify the disparities observed in the container closure report as the results of few container compatibility test stated that the 2ml type I glass bottle are compatible for the product, further the final conclusion of report claimed that the paracetamol injection 1mg/100ml is stable with the type I glass bottles.

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

259.	Name, address of Applicant / Importer	M/s. Zhangjiakou Dongfang Pharmaceutical Pakistan Pvt. Ltd. D-2,2nd Floor, West Land Trade Centre, Plot No. C-5, Block 7/8, K C H S U, Shaheed-e-Millat Road Karachi
	Details of Drug Sale License of importer	License No: 0067 Address: D-2,2nd Floor, West Land Trade Centre, Plot No. C-5, Block 7/8, K C H S U, Shaheed-e-Millat Road Karachi. Address of Godown: D-2,2nd Floor, West Land Trade Centre, Plot No. C-5, Block 7/8, K C H S U, Shaheed-e-Millat Road Karachi. Validity: 09/10/2022 Status: Stock, Exhibit to sell, License to sell drugs as distributor by way of wholesale Renewal: Our license has been renewed and the details written above are for the renewed licenses.
	Name and address of marketing authorization holder (abroad)	M/s. Lunan Better Pharmaceutical Co. Ltd. No. 243 Yinqueshan Road, Linyi, Shandong, China

	Name, address of manufacturer(s)	Name of Manufacturer: M/s. Lunan Better Pharmaceutical Co. Ltd. Address: No. 243 Yinqueshan Road, Linyi, Shandong, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized CoPP certificate No: NO. SHANDONG 20210104 Dated 06-07-2021 issued by The Fifth Branch of Regional Inspection Shandong Food and Drug Administration valid till 26-06-2023. Firm has submitted GMP certificate no.HB20190552 of Manufacturer M/s. Lunan Better Pharmaceutical Co. Ltd. No. 243, Yinqueshan Road, Linyi, Shandong and the certificate remain valid until; 25-11-2023.
	Details of letter of authorization / sole agency agreement	Letter of Authorization submitted by the firm in which it is specifies that M/s.Lunan Better Pharmaceutical Co. Ltd. authorize to get registration of their product (Latanoprost Eye Drops) and authorized distributor for the product to make registration with DRAP and to sale, distribute, market & quote in any Government, semi-Government and Semi-Government and Autonomous Bodies & Private Sectors in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.no.23664 dated 22-08-2022
	Details of fee submitted	PKR 150,000/-: vide slip no. 51511233694 dated 15-08-2022.
	The proposed proprietary name / brand name	Latanoprost Eye Drops 2.5ml:0.125mg (0.005%)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2.5ml contains: Latanoprost……0.125mg
	Pharmaceutical form of applied drug	Ophthalmic solution
	Pharmacotherapeutic Group of (API)	Prostaglandin F2α Analogue (S01EE01)
	Reference to Finished product specifications	In-house
	Proposed Pack size	2.5ml of ophthalmic solution packed in 5ml LDPE eye drop bottle
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	USFDA Approved (XALATAN® (latanoprost ophthalmic solution) 0.005%, for topical ophthalmic use)
	For generic drugs (me-too status)	Xalatan Eye Drops of M/s. Pfizer Pakistan Pvt. Ltd., Karachi (Reg.no. 021125)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. Yonsung Fine Chemicals Co. Ltd. 207 Sujeong-Ro,Jangan-Myeon,Hwaseong-Si,Gyeonggi D0,18581,Republic of Korea.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The accelerated stability data is conducted at 5°C ± 3°C and the real time stability study is conducted at -20± 5°C. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence studies report against the innovator product XALATAN® (latanoprost ophthalmic solution) 0.005%, for topical ophthalmic use.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	2.5ml:0.125mg packaged in 5ml LDPE Medicinal Eye Drops bottle (containing bottle, inner stopper and bottle cap)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 25°C ±2°C / 60% ± 5% RH for 6 months. The real time stability study data is conducted at 5°C±3°C. The real time stability study data of 3 batches is for 36 months

Evaluation by PEC:

S.no.	Section	Observations/Deficiencies/ Short-comings

1.	1.3.3	Submit valid, original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate issued by relevant regulatory authority of country of origin, since the submitted CoPP was expired on 06-06-2023.
2.	1.3.4	Submit valid Drug Sale License since the submitted DSL was expired on 09/10/2022.
3.	3.2.S.4.1-3.2.S.4.2	Provide specification and analytical procedure of drug substance used for analysis by drug product manufacturer.
4.	3.2.S.4.3	Provide analytical method validation report performed by drug product manufacturer.
5.	3.2.S.4.4	Provide batch analysis report of drug substance by the drug product manufacturer.
6.	3.2.P.2	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.
7.	3.2.P.8	How you have assess the extent of water loss from the semi-permeable container, since ICH guidelines recommend appropriate information should be provided to assess the extent of water loss, If the drug product is packaged in a semi-permeable container.

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

260.	Name, address of Applicant / Importer	M/s. Martin Dow Limited Plot no.37 Sec: 19 K.I.A. Karachi
	Details of Drug Sale License of importer	License No: 565 Address: Plot no.37 Sec: 19 K.I.A. Karachi Address of Godown: 1. 1st Floor Plot no. 211 Sec:23 K.I.A. Karachi 2. Plot no.32 Sec: 16 K.I.A. Karachi Validity: 16/06/2024 Status: Stock, Exhibit to sell, License to sell drugs as distributor by way of wholesale
	Name and address of marketing authorization holder (abroad)	M/s. ANFARM HELLAS S.A. Administration Office: 4 ACHAIAS STR & TRIZINIAS, Kifissia Attiki,14564, Greece. Manufacturing Site: 61st Km, NAT. RD. ATHENS-LAMIA,Schimatari Viotias,32009,Greece
	Name, address of manufacturer(s)	Name of Manufacturer: M/s. ANFARM HELLAS S.A. Manufacturing Site: 61st Km, NAT. RD. ATHENS-LAMIA,Schimatari Viotias,32009,Greece.
	Name of exporting country	Greece
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized CoPP certificate No: 67953 Dated 01-07-2022 issued by National Organization for Medicines(EOF) 284 Mesogeion Ave.15562 Holargos Attica, Greece. CoPP did not confirm the freely available status of applied product in the exporting country. Firm has submitted GMP certificate no.8652/23-02-2021 of Manufacturer M/s. ANFARM HELLAS S.A. Manufacturing Site: 61st Km, NAT. RD. ATHENS-LAMIA, Schimatari Viotias,32009, Greece. Dated 22-03-2019 and the certificate remain valid for three years.
	Details of letter of authorization / sole agency agreement	Sole agency agreement submitted by the firm in which it is specifies that M/s. ANFARM HELLAS S.A. Administration Office: 4 ACHAIAS STR &

		TRIZINIAS, Kifissia Attiki,14564, Greece. Confirm that Martin Dow Limited, Karachi is the sole authorized importer of the Sugadex Solution for Injection 100mg/ml.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.no.22951 dated 15-08-2022
	Details of fee submitted	PKR 150,000/-: vide slip no. 8496974962 dated 22-07-2022.
	The proposed proprietary name / brand name	SUGADEX Injection 200mg/2ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Sugammadex Sodium eq. to Sugammadex…100mg
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	Antidotes (Selective relaxant binding agent)
	Reference to Finished product specifications	In-house
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (BRIDION 200mg Base/2ml)
	For generic drugs (me-too status)	SUGA Injection 200mg/2ml of M/s. Brookes Pharma (Pvt) Ltd., Karachi approved in 324th meeting of Registration Board.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. Teva Pharmaceuticals Industries Ltd. 124 Dvora HaNevi'a Tel Aviv-Jaffa 6944020, Isreal (DMF HOLDER) Manufacturing Site: PLIVA Croatia Ltd. Production

		SM,10291 Prigorje Brdovecko Croatia.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C/75± 5% RH and the real time stability study is conducted at 25°C ± 2°C/60 ± 5% RH. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence studies report against the innovator product Bridion Injection of M/s. Merck Sharp & Dhome Ltd. (2ml Lot no. S018704,R030867,R014496)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	3ml Type-I clear glass vial and a chlorobutyl rubber stopper, sealed with an aluminium cap with a plastic flip off lid.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 75% ± 5% RH. The real time stability study data of 3 batches is for 24 months

Evaluation by PEC:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid, original and legalized Free Sale certificate issued by relevant regulatory authority of country of origin, since the submitted CoPP stated that the applied product is not freely available in the exporting country.	Firm submitted a new CoPP of certificate no. 138376 issue dated 20-12-2022 by the certifying authority National Organization for Medicines (E.O.F) 284 Mesogeion Ave. 155 62 Holagros Attica, Greece, in which it is evident that the applied product is freely available in the country of origin.
2.	Submit valid GMP certificate of Manufacturer Abroad since the submitted GMP certificate was expired in 2022.	Firm submitted a copy of valid GMP certificate of Manufacturer Abroad.

3.	Submitted sole agency agreement and CoPP reflects that the drug product is imported in 1ml pack size, while the product part of module-3 reveals that the drug product is manufactured in 2ml pack size, clarify the disparity regarding the volume of injection along with supporting legalized document.	Firm replied that per ml of injection strength is mentioned in the sole agency agreement and CoPP while the applied pack size is 1's in presentation of 2ml ampoule.
4.	Submit complete stability data of three batches till the claimed shelf life, since you have submitted the real time stability data of 24 months while the claimed shelf is of 36 months.	Submitted.

Decision: Approved subject to compliance to current import policy for finished drugs.

261.	Name, address of Applicant / Importer	M/s. Ghazali Brothers 19-SR-7 Combell street Azzainab Court 1st Floor, Karachi
	Details of Drug Sale License of importer	License No: 143 Address: 19-SR-7 Combell street Azzainab Court 1st Floor, Karachi Address of Godown: 1. S.No. 14G/Floor Karinji & others Plot WO7/15 Napier 2. 2D,2nd Floor Karimji & others Plot No.WO7/15, N. Napier Road, Karachi Validity: 26/10/2023 Status: Stock, Exhibit to sell, License to sell drugs as distributor by way of wholesale
	Name and address of marketing authorization holder (abroad)	M/s. Anhui Ocean Pharmaceutical Co. Ltd. No. 1918 Longhua Road, Bengbu, Anhui Province, China
	Name, address of manufacturer(s)	M/s. Anhui Ocean Pharmaceutical Co. Ltd. No. 1918 Longhua Road, Bengbu, Anhui Province, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized CoPP certificate No: Nil Dated 29-07-2022 and valid for 5 years. CoPP did not mentioned the issuing authority name neither the certificate number. Firm has submitted GMP certificate no.8652/23-02-2021 of Manufacturer M/s. ANFARM HELLAS S.A. Manufacturing Site: 61st Km, NAT. RD. ATHENS-LAMIA, Schimatari Viotias,32009, Greece. Dated 22-03-2019 and the certificate remain valid for three years.
	Details of letter of authorization / sole agency agreement	Sole agency agreement submitted by the firm in which it is specifies that M/s. Anhui Ocean Pharmaceutical Co. Ltd. No. 1918 Longhua Road, Bengbu, Anhui Province, China Confirm that Ghazali Brothers, Karachi is the sole agent and is authorize to promote ,register, commercialize and distribute our company's prodcuts in the territory of Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.no.22875 dated 12-08-2022
	Details of fee submitted	PKR 150,000/-: vide slip no.94574666 dated 14-04-2022.
	The proposed proprietary name / brand name	**Dexamethasone Sodium Phosphate Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Dexamethasone sodium phosphate …4mg
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	Glucocorticoid
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	DMX 4mg/ml Injection Reg. No. 103653 M/s Rotex Pharma (Pvt.) Ltd. Islamabad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Zhejiang Xianju Pharmaceutical Co., Ltd. No.1 Xian Yao Road, Xianju, Zhejiang,China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C/75± 5% RH and the real time stability study is conducted at 25°C ± 2°C/60 ± 5% RH. The stability study data is till

		48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence studies report against the reference product of M/s. Aspen Pharma Trading Limted, China, Xinxiang Changle Pharmaceuticals Co. Ltd. China, M/s. Zhejang Xianju Pharmaceuticals Co. Ltd. China.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Low borosilicate glass ampoule filled with clear colourless injectable solution.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 75% ± 5% RH. The real time stability study data of 3 batches is for 36 months

Evaluation by PEC:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	1.3.3	• Submit valid legalized GMP certificate of Manufacturer Abroad issued by the competent authority of country of origin. • Certificate number and the name of issuing authority is not mentioned on the submitted CoPP, Submit valid, original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate issued by relevant regulatory authority of country of origin mentioning certificate number and name of issuing authority.
2.	3.2.S.4.1	• Justify for keeping the high water content limit of drug substance NMT 15% by the drug product manufacturer, when the USP monograph of dexamethasone sodium phosphate and specification of drug substance by substance manufacturer recommends the water content limit NMT 10%. Further the monograph of drug substance is present in both USP and BP, justify for complying the Chinese pharmacopeia (CP2015). • Drug substance manufacturer recommends UV method for assay of drug substance while the drug product manufacturer have performed the assay of drug substance via HPLC method, justify for adopting the different assay procedure of drug substance by drug product manufacturer from the assay procedure recommended by the drug substance manufacturer.
3.	3.2.S.4.4	Submit COA of drug substance by the drug substance manufacturer.
4.	3.2.S.5	Provide certificate of analysis of reference standard /working standard used for testing of the drug substance.
5.	3.2.S.7	Justify for keeping the wider water content limit i.e. NMT 16.0% while performing the stability studies of drug substance when the drug substance manufacturer recommends the water content limit NMT 10% in the specification table of drug substance.

6.	3.2.P.1.1	Label claim on the CoPP and specifying in the section 3.2.P.1 is not in accordance with the label claim of innovator product approved in USFDA neither complying the definition of Monograph of Dexamethasone sodium phosphate Injection. Amend the label claim in accordance with the USP i.e. Each mL contains dexamethasone sodium phosphate equivalent to dexamethasone phosphate 4 mg or dexamethasone 3.33 mg.
7.	3.2.P.5.2	Submit detailed analytical procedure of drug product that is actually used for the analysis of applied product instead of submitting the copy of USP monograph of dexamethasone sodium phosphate Injection.
8.	3.2.P.5.3	Submit the complete analytical method verification report instead of only submitting the summary table of validation procedure.
9.	3.2.P.7	Clarify the volume size of primary container either the volume capacity of glass container is of 1ml or more.
10.	3.2.P.8	Provide quantitative results in stability data sheets in section 3.2.P.8.3 as per the decision of 293rd meeting of Registration Board, which states that "*For quantitative tests, actual numerical results should be provided rather than vague statements such as "within limits" or "conforms*".

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

262.	Name, address of Applicant / Importer	M/s. Calory Pharma 75-B, Circular street No.13 Central Lane Phase-II DHA Karachi.
	Details of Drug Sale License of importer	License No: 110 Address: 75-B, Circular street No.13 Central Lane Phase-II DHA Karachi. Address of Godown: NA Validity: 06-07-2023 Status: Stock, Exhibit to sell, License to sell drugs as distributor by way of wholesale
	Name and address of marketing authorization holder (abroad)	M/s. Biem Ilac San.ve Tic. A.S Turgut Reis Cad.no:21 06570 Tandogan/Ankara.
	Name, address of manufacturer(s)	M/s. Idol Ilac Dolum San. Ve Tic. A.S. Davutpasa Cad. Cevealibey Sk. No:20 Topkapi/Istanbul/TURKEY.
	Name of exporting country	Turkiye
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized CoPP certificate No: 2022/1247 dated 09-05-2022, valid for 2 years from the date of issue confirming the freely available status of product in the market of exporting country issued by the Turkish medicine and medical Agency. Firm has submitted GMP certificate no. TR/GMP/2021/335 of Manufacturer /s. Idol Ilac Dolum San. Ve Tic. A.S. Davutpasa Cad. Cevealibey Sk. No:20 Topkapi/Istanbul/TURKEY. Based on inspection Dated 17-20/09/2018 and the certificate remain valid for three years.
	Details of letter of authorization / sole agency agreement	Sole agency agreement submitted by the firm in which it is specifies that M/s. BIEM Ilac Sanayi ve Ticaret A.S., Located at Anittepe Mah. Turgut Reis Cad. No: 21 Tandogan, Cankaya, Ankara/Turkey hereby authorize Calory Pharma which is registered in the 75-B, Circular street No.13 Central Lane Phase-II DHA Karachi. To promote, market,sell and perform the registration procedures and other similar activities to the producy VOTRON (Palonosetron) 250mcg/5ml.

	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.no.23963 dated 24-08-2022
	Details of fee submitted	PKR 150,000/-: vide slip no.83102401930 dated 29-06-2022.
	The proposed proprietary name / brand name	VOTRON 250mcg/5ml solution for IV Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml vial contains: 0.280 mg Palonosetron Hydrochloride eq. to 0.250mg Palonosetron
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	Antiemetic and antinauseant (Advanced and selective 5-HT3 receptor antagonist.
	Reference to Finished product specifications	In-House
	Proposed Pack size	One 5ml vial per pack
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Palonosetron as hydrochloride 250 microgram/5 mL solution for injection, TGA approved.
	For generic drugs (me-too status)	Arista Injection 0.25mg/5ml, S.J & G. Fazul Ellahie, Reg. No. 070580.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. Qilu Pharmaceuticals Co. Ltd. No.243 Gong Ye Bei Road, Jinan, Shandong Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C/75± 5% RH and the real time stability study is conducted at 30°C ± 2°C/65 ± 5% RH. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence studies report against the innovator product Aloxi Injection 25mg/5ml.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I glass 5ml vial with bromobutyl rubber, grey colored flip off closure.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 75% ± 5% RH. The real time stability study data of 3 batches is for 36 months.

Evaluation by PEC:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	1.3.3	Submit valid legalized GMP certificate of Manufacturer Abroad issued by the competent authority of country of origin.
2.	3.2.S.4.1	• How can the drug substance manufacturer comply Eur. Ph. for the analysis of most of the quality parameters of drug substance when the monograph of drug substance is not present in European Pharmacopeia. Further, justify for not adopting the USP specification for drug substance since the monograph of Palonosetron hydrochloride is present in USP. • Justify for not including the sterility test, microbial enumeration tests and specified microorganism test when the drug substance is used for manufacturing sterile pharmaceutical product. • Scientific justification is required for using potentiometric titration technique for assay of drug substance. • Provide specification and analytical procedure of drug substance used for analysis by drug product manufacturer
3.	3.2.S.4.3	• Assay procedure given in section 3.2.S.4.2 indicates that the assay of drug substance has been performed via potentiometric titration while the validation report of assay procedure reflects that the HPLC technique has used for assay of drug substance clarification is required regarding the disparity observed related to the assay technique.

		• Provide analytical method validation report performed by drug product manufacturer.
4.	3.2.S.4.4	Submit batch analysis report of drug substance performed by drug product manufacturer.
5.	3.2.P.2.2.1	Please specify the details of manufacturer of originator product "Aloxi" against which you have established the pharmaceutical equivalence of applied product since the discontinued marketing status of Aloxi is observed in the USFDA database of drug product.

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

CASES OF LOCAL MANUFACTURING OF FORM 5-F:

263.	Name, address of Applicant / Marketing Authorization Holder	M/s. Genix Pharma (Private) Ltd. 44-45-B Korangi Creek Road Karachi
	Name, address of Manufacturing site.	M/s. Genix Pharma (Private) Ltd. 44-45-B Korangi Creek Road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted GMP certificate no.46/2021-DRAP(K) dated 07th October,2021.
	Evidence of approval of manufacturing facility	Firm submitted GMP certificate no.46/2021-DRAP(K) dated 07th October,2021 in which Syrup/Oral Suspension section is specified in the list of approved section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27403 dated 27-09-2022
	Details of fee submitted	Rs. 75,000/- vide slip no. 70273076715 dated 22-09-2022
	The proposed proprietary name / brand name	**Baclast 5mg/5ml Oral solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Baclofen…….5mg
	Pharmacotherapeutic Group of (API)	Skeletal Muscle Relaxant (gamma-aminobutyric acid (GABA-ergic) agonist)
	Pharmaceutical form of applied drug	Oral Solution
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	60ml,100ml,200ml & 300ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA (Baclofen 5 mg/5 mL Oral Solution) Approved in 300ml pack volume.
	For generic drugs (me-too status)	NA

	Name and address of API manufacturer.	M/s. Panchsheel Organics Limited B6-B7,Sector-C,Sanwer Road, Industrial Estate Indore (M.P), India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 18 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against the reference product Baclofen oral solution 5mg/5ml oral solution of M/s. Advanz Pharma (Batch no. E5896)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s. Panchsheel Organics Limited B6-B7,Sector-C,Sanwer Road, Industrial Estate Indore (M.P), India		
API Lot No.	BCF/2122007		
Description of Pack (Container closure system)	Clear,colorless solution with raspberry flavour filled in amber glass bottle 30ml		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21SB(B)-167-01	21SB(B)-168-02	21SB(B)-169-03
Batch Size	75 BOTTLES	75 BOTTLES	75 BOTTLES
Manufacturing Date	10-2021	10-2021	10-2021

No. of Batches		03
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No.INDBGMP202201594) issued dated 02-March-2022 and valid for 5 years from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of DRAP attested invoice related to the procurement of API.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Therapeutic indications:
Baclofen 5 mg/5 mL Oral Solution is indicated for the relief of spasticity of voluntary muscle resulting from such disorders as: multiple sclerosis, other spinal lesions, e.g. tumours of the spinal cord, syringomyelia, motor neurone disease, transverse myelitis, traumatic partial section of the cord. Baclofen 5 mg/5 mL Oral Solution is also indicated in adults and children for the relief of spasticity of voluntary muscle arising from e.g. cerebrovascular accidents, cerebral palsy, meningitis, traumatic head injury. Patient selection is important when initiating Baclofen 5 mg/5 mL Oral Solution therapy; it is likely to be of most benefit in patients whose spasticity constitutes a handicap to activities and/or physiotherapy. Treatment should not be commenced until the spastic state has become stabilised.

Posology and method of administration
Before starting treatment with Baclofen 5 mg/5 mL Oral Solution it is prudent to realistically assess the overall extent of clinical improvement that the patient may be expected to achieve. Careful titration of dosage is essential (particularly in the elderly) until the patient is stabilised. If too high a dose is initiated or if the dosage is increased too rapidly side effects may occur. This is particularly relevant if the patient is ambulant in order to minimise muscle weakness in the unaffected limbs or where spasticity is necessary for support. Adults: The following gradually increasing dosage regimen is suggested, but should be adjusted to suit individual patient requirements. 5mg three times a day for three days 10mg three times a day for three days 15mg three times a day for three days 20mg three times a day for three days Satisfactory control of symptoms is usually obtained with doses of up to 60mg daily, but a careful adjustment is often necessary to meet the requirements of each individual patient. The dose may be increased slowly if required, but a maximum daily dose of more than 100mg is not advised unless the patient is in hospital under MHRA PAR; BACLOFEN 5 MG/5 ML ORAL SOLUTION, PL 06464/2354 13 careful medical supervision. Small frequent dosage may prove better in some cases than larger spaced doses. Also some patients benefit from the use of Baclofen 5 mg/5 mL Oral Solution only at night to counteract painful flexor spasm. Similarly, a single dose given approximately 1 hour prior to performance of specific tasks such as washing, dressing, shaving, physiotherapy, will often improve mobility. Once the maximum recommended dose has been reached, if the therapeutic effect is not apparent within 6 weeks a decision whether to continue with Baclofen 5 mg/5 mL Oral Solution should be taken.

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Provide the evidence of reference product approved in reference regulatory agencies in the volume size of 60ml,100ml &200ml.	Firm replied that reference product is available only in 300ml pack size. However for patient compliance and affordability we have requested pack size of 60ml,100ml and 200ml.

2.	You have mentioned innovator's specification in section 1.5.6 in module 1 while the drug product monograph is available in BP. Revise the specifications along with submission of requisite fee.	Firm replied they have performed the stability studies as per BP method but they skipped to mention BP specification therefore they have revised the specification as per BP. Requisite fee of Rs.7500/- has submitted vide deposit slip no. 69383266679 dated 19-01-2024. However, the analytical procedure of drug product given in section 3.2.P.5.2 specifically assay procedure is different from method recommended by the BP monograph of Baclofen Oral Solution.
3.	Drug Substance manufacturer claimed IP specification for the drug substance while you have complied BP specification, clarify for using different specification for the drug substance from that claimed by drug substance manufacturer.	Firm replied that drug substance in Drug Master File Claim both IP & BP. However, the monograph of Baclofen drug substance is not present in IP, Eleventh Edition,2022.
4.	Submit complete real time stability data of drug substance till claimed re-test date, since you have only submitted the data of 18 months.	Submitted
5.	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Submitted
6.	Submit the analysis report/COA of excipients propylene glycol and sorbitol which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-42/2023-QC dated 1st, December,2023.	Firm submitted raw material analytical report of Propylene glycol and sorbitol which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol including the COA of vendor of raw material Propylene glycol and sorbitol. However COA of sorbitol from raw material manufacturer did include the impurity testing related to the presence of ethylene glycol and diethylene glycol.
7.	Storage condition specified by the reference product and BP monograph of "Baclofen Oral Solution) is "Baclofen oral solution should be stored below 25°C, while the storage condition mentioned by you is store below 30°C, Justify the storage condition recommended by you for your applied product.	Firm replied that mistakenly it is written as store below 30°C the actual correct storage is store below 25°C. Revised SOP is submitted.
8.	Justify for not adopting the BP specifications for the drug product when the monograph of Baclofen Oral Solution is present in BP.	Firm replied they have performed the stability studies as per BP method but they skipped to mention BP specification therefore they have revised the specification as per BP. Requisite fee of Rs.7500/- has submitted vide deposit slip no. 69383266679 dated 19-01-2024. However, the analytical procedure of drug product given in section 3.2.P.5.2 specifically assay procedure is different from method recommended by the BP monograph of Baclofen Oral Solution.
9.	Submit data in section 3.2.P.8.1 as per the guidance document approved by Registration Board which specifies that "Summary of additional stability studies (if	Firm submitted the in-use stability data of 28 days. Stability study has been performed on 30ml pack size, which is not included in the demanded pack size.

	applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided".	
Decision: Deferred for revision of analytical procedure of drug product specifically assay method in accordance with BP monograph of "Baclofen Oral Solution" and submit the performance report in accordance with revised analytical method at next time point of long term stability studies.		
264.	Name, address of Applicant / Marketing Authorization Holder	M/s. Genix Pharma (Private) Ltd. 44-45-B Korangi Creek Road Karachi
	Name, address of Manufacturing site.	M/s. Genix Pharma (Private) Ltd. 44-45-B Korangi Creek Road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted GMP certificate no.46/2021-DRAP(K) dated 07th October,2021.
	Evidence of approval of manufacturing facility	Firm submitted GMP certificate no.46/2021-DRAP(K) dated 07th October,2021 in which Syrup/Oral Suspension section is specified in the list of approved section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27403 dated 27-09-2022
	Details of fee submitted	Rs. 75,000/- vide slip no. 70273076715 dated 22-09-2022
	The proposed proprietary name / brand name	**Baclast 10mg/5ml Oral solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Baclofen…….10mg
	Pharmacotherapeutic Group of (API)	Skeletal Muscle Relaxant (gamma-aminobutyric acid (GABA-ergic) agonist)
	Pharmaceutical form of applied drug	Oral Solution
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	60ml,100ml,200ml & 300ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA (Baclofen 10mg/5 mL Oral Solution) Approved in 300ml pack volume.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s. Panchsheel Organics Limited B6-B7,Sector-C,Sanwer Road, Industrial Estate Indore (M.P), India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature,

		structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 18 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against the reference product Baclofen oral solution 10mg/5ml oral solution of M/s. Thames Laboratories (Batch no.HFCR0004)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Panchsheel Organics Limited B6-B7,Sector-C,Sanwer Road, Industrial Estate Indore (M.P), India		
API Lot No.	BCF/2122007		
Description of Pack (Container closure system)	Clear,colorless solution with raspberry flavour filled in amber glass bottle 30ml		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21SB(B)-170-01	21SB(B)-171-02	21SB(B)-172-03
Batch Size	75 BOTTLES	75 BOTTLES	75 BOTTLES
Manufacturing Date	10-2021	10-2021	10-2021
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No.INDBGMP202201594) issued dated 02-March-2022 and valid for 5 years from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of DRAP attested invoice related to the procurement of API.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Provide the evidence of reference product approved in reference regulatory agencies in the volume size of 60ml,100ml &200ml.	Firm replied that reference product is available only in 300ml pack size. However for patient compliance and affordability we have requested pack size of 60ml,100ml and 200ml.
2.	You have mentioned innovator's specification in section 1.5.6 in module 1 while the drug product monograph is available in BP. Revise the specifications along with submission of requisite fee.	Firm replied they have performed the stability studies as per BP method but they skipped to mention BP specification therefore they have revised the specification as per BP. Requisite fee of Rs.7500/- has submitted vide deposit slip no. 69383266679 dated 19-01-2024. However, the analytical procedure of drug product given in section 3.2.P.5.2 specifically assay procedure is different from method recommended by the BP monograph of Baclofen Oral Solution.
3.	Drug Substance manufacturer claimed IP specification for the drug substance while you have complied BP specification, clarify for using different specification for the drug substance from that claimed by drug substance manufacturer.	Firm replied that drug substance in Drug Master File Claim both IP & BP. However, the monograph of Baclofen drug substance is not present in IP, Eleventh Edition,2022.
4.	Submit complete real time stability data of drug substance till claimed re-test date, since you have only submitted the data of 18 months.	Submitted
5.	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Submitted
6.	Submit the analysis report/COA of excipients propylene glycol and sorbitol which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by	Firm submitted raw material analytical report of Propylene glycol and sorbitol which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol including the COA of vendor of raw material Propylene glycol and sorbitol.

	DRAP vide letter No. F.3-42/2023-QC dated 1st, December,2023.	However COA of sorbitol from raw material manufacturer did include the impurity testing related to the presence of ethylene glycol and diethylene glycol.
7.	Storage condition specified by the reference product and BP monograph of "Baclofen Oral Solution) is "Baclofen oral solution should be stored below 25°C, while the storage condition mentioned by you is store below 30°C, Justify the storage condition recommended by you for your applied product.	Firm replied that mistakenly it is written as store below 30°C the actual correct storage is store below 25°C. Revised SOP is submitted.
8.	Justify for not adopting the BP specifications for the drug product when the monograph of Baclofen Oral Solution is present in BP.	Firm replied they have performed the stability studies as per BP method but they skipped to mention BP specification therefore they have revised the specification as per BP. Requisite fee of Rs.7500/- has submitted vide deposit slip no. 69383266679 dated 19-01-2024. However, the analytical procedure of drug product given in section 3.2.P.5.2 specifically assay procedure is different from method recommended by the BP monograph of Baclofen Oral Solution.
9.	Submit data in section 3.2.P.8.1 as per the guidance document approved by Registration Board which specifies that "Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided".	Firm submitted the in-use stability data of 28 days. Stability study has been performed on 30ml pack size, which is not included in the demanded pack size.

Decision: Deferred for revision of analytical procedure of drug product specifically assay method in accordance with BP monograph of "Baclofen Oral Solution" and submit the performance report in accordance with revised analytical method at next time point of long term stability studies.

265.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted GMP certificate no.70/2021-DRAP(FID/2061717-540) dated 08/09/2021.
	Evidence of approval of manufacturing facility	Firm submitted GMP certificate no.70/2021-DRAP(FID/2061717-540) dated 08/09/2021. in which Tablet section is specified in the list of approved section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 23515 dated 19-08-2022

	Details of fee submitted	Rs. 30,000/- vide slip no. 183897907049 dated 29-11-2021
	The proposed proprietary name / brand name	**Zapnal 10mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Olanzapine …….10mg
	Pharmacotherapeutic Group of (API)	Amost white coloured, film coated round plain tablets
	Pharmaceutical form of applied drug	Atypical antipsychotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zyprexa 10mg tablet by M/s Eli lilly and company limited, USFDA Approved.
	For generic drugs (me-too status)	Olepra 10mg tablet by M/s Genetics Pharmaceuticlas Pvt. Ltd, Reg. No. 038672
	Name and address of API manufacturer.	M/s RAMPEX LABS PRIVATE LIMITED Plot No. 34-C Jawaharlal Nehru Pharma City PARAWADA.VISAKHAPATNAM – 531 019, ANDHRA PRADESH, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(LAN-4P/00613, LAN-4P/00713, LAN-4P/00813)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence report and Comparative dissolution profile against the comparator product Olepra 10mg Tablet Genetics Pharmaceuticals Pvt. Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s RAMPEX LABS PRIVATE LIMITED Plot No. 34-C Jawaharlal Nehru Pharma City PARAWADA.VISAKHAPATNAM – 531 019, ANDHRA PRADESH, INDIA.		
API Lot No.	LAN/0040420		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TZA001	TZA002	TZA003
Batch Size	2500 tab	2500 tab	2500 tab
Manufacturing Date	01-2021	01-2021	01-2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 21/VP/AP/2011/B/CC/R issued by FDCA valid till 29/09/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.8623/2020/DRAP-AD-CD(I&E) dated 03/07/2020 is submitted wherein the permission to import different APIs including olanzapine for the purpose of test/analysis and stability studies is granted. ZHI-CI/4506/0520, DATE: 14-05-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Provide raw data sheets and chromatograms of analytical method	Firm submitted the analytical procedure along verification report in accordance with USP monograph.

	verification report as the submitted report did not specify the assay procedures.	
2.	Comparative dissolution profile report of drug product revealed that at 30 minutes not more than 80% drug release in all three physiological medium, justify the results with the acceptance limit of dissolution i.e. NLT 80% in 30min using pH 1.2 as the recommended dissolution medium as per USP monograph.	Firm submitted the revised CDP report in which more than 80% drug release within 30 minutes.
3.	Adapt the acceptance limit of dissolution in term of Q, since the USP monograph specify the limit with Q value i.e. NLT 80% (Q) of the labelled amount of olanzapine dissolved.	Revised specification submitted by the firm.
4.	Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Submit valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	API lot no. LAN/0040420 has been used in manufacturing of each batch of drug product. GMP certificate of API manufacturer M/s.RAMPEX Labs Pvt. Ltd., India has been submitted by the firm which was valid till 20-04-2021, however the manufacturing license of manufacturer is valid till 29-09-2024 as written on the said GMP certificate.

Decision: Approved. Applicant shall submit PKR 7500/- pre-registration variation fee for revision of specification, prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023 before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

266.	Name, address of Applicant / Marketing Authorization Holder	M/s Jawa Pharmaceuticals Private Limited 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore, Punjab, Pakistan
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Private Limited 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore, Punjab, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 06-07-2020 based on inspection conducted on 04-03-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 25-06-2019 specifying Tablet Psychotropic Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 25349 dated 07-09-2022

	Details of fee submitted	Rs.30,000/- dated 18-07-2022
	The proposed proprietary name / brand name	**Esparm 20mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Escitalopram (as oxalate) ……. 20mg
	Pharmacotherapeutic Group of (API)	Anti-psychotic
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lexapro Tablet by Custom Pharmaceuticals Limited, U.K ,NDA 21-323
	For generic drugs (me-too status)	Es-Pramcit Tablet by Nabi Qasim Pharmaceuticals (Pvt), Ltd (Reg.No. 061661)
	Name and address of API manufacturer.	Zhejiang Haisen Pharmaceutical Co., Ltd. AXiangtan Village, Liushi Street, Dongyang City, Zhejiang Province 322104, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Es-pramcit manufactured by Nabi -Qasim Pharmaceuticals (Pvt), Ltd.

	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Zhejiang Haisen Pharmaceutical Co., Ltd. AXiangtan Village, Liushi Street, Dongyang City, Zhejiang Province 322104, China.		
API Lot No.	3619102201		
Description of Pack (Container closure system)	Tablets are packed in the PVC/aluminum foil blister packs.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6,9,12 (Months)		
Batch No.	T01	T02	T03
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	03-2021	03-2021	03-2021
No. of Batches	03		

267.	Name, address of Applicant / Marketing Authorization Holder	M/s Jawa Pharmaceuticals Private Limited 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore, Punjab, Pakistan
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Private Limited 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore, Punjab, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 06-07-2020 based on inspection conducted on 04-03-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 25-06-2019 specifying Tablet Psychotropic Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 25348 dated 07-09-2022
	Details of fee submitted	Rs.30,000/- dated 18-07-2022
	The proposed proprietary name / brand name	**Esparm 10mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Escitalopram (as oxalate) ……. 10mg
	Pharmacotherapeutic Group of (API)	Anti-psychotic
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lexapro Tablet by Custom Pharmaceuticals Limited, U.K ,NDA 21-323

	For generic drugs (me-too status)	Es-Pramcit Tablet by Nabi Qasim Pharmaceuticals (Pvt), Ltd (Reg.No. 061661)
	Name and address of API manufacturer.	Zhejiang Haisen Pharmaceutical Co., Ltd. AXiangtan Village, Liushi Street, Dongyang City, Zhejiang Province 322104, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Es-pramcit manufactured by Nabi -Qasim Pharmaceuticals (Pvt), Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Zhejiang Haisen Pharmaceutical Co., Ltd. AXiangtan Village, Liushi Street, Dongyang City, Zhejiang Province 322104, China.
API Lot No.	3619102201
Description of Pack (Container closure system)	Tablets are packed in the PVC/aluminium foil blister packs.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6,9,12 (Months)		
Batch No.	T01	T02	T03
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	02-2021	02-2021	02-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Escitalopram: Zhejiang Haisen Pharmaceutical Co., Ltd. AXiangtan Village, Liushi Street, Dongyang City, Zhejiang Province 322104, China.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of ADC Permission by AD (I&E) DRAP, Lahore.13.01.2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section #	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate of drug substance manufacturer, issued by relevant regulatory authority of country of origin.	Submitted valid GMP certificate of drug substance.
3.2.S.4.3	Submit drug substance specifications, analytical procedure and Batch analysis certificate form drug substance manufacturer.	Firm submitted drug substance specifications, analytical procedure and Batch analysis certificate form drug substance manufacturer.
3.2.P.8.3	Submit following: • Analytical record for drug product stability studies including raw data sheets, batch manufacturing record.	Submitted

Decision: Registration Board approved the applications of Espram 10mg & Espram 20mg tablets.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Cases of New sections received on Form 5-F:

268.	Name, address of Applicant / Marketing Authorization Holder	M/s. Genetics Pharmaceuticals (Pvt.) Ltd. Address: 539-A, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan
	Name, address of Manufacturing site.	M/s. Genetics Pharmaceuticals (Pvt.) Ltd. Address: 539-A, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted GMP certificate no.93/2022-DRAP(AD-5312766601) dated 06th June,2022.
	Evidence of approval of manufacturing facility	Firm submitted grant of additional section letter (new section) dated 25th October,2023 of Syrup section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 14717 dated 12-06-2023
	Details of fee submitted	Rs.30,000/- vide slip no. 677708090604 dated 10-05-2023
	The proposed proprietary name / brand name	**Lepsi Oral Solution 100mg / 1mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1mL Contains: Levetiracetam 100mg
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Pharmaceutical form of applied drug	Oral Solution
	Reference to Finished product specifications	USP specification
	Proposed Pack size	100mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	U.S. FDA Keppra Levetiracetam 100mg Oral Solution of UCB Inc.
	For generic drugs (me-too status)	Epicetam Oral solution Each 1mL contains: Levetiracetam 100mg of CCL Pharmaceuticals Pvt. Ltd (Registration number: 077018)
	Name and address of API manufacturer.	Manufacturer: Shangyu Jingxin Pharmaceutical Co., Ltd. Manufacturing site and address: No. 31 Weisan Road, Hangzhou Bay Shangyu Economic and Technological Development Area, Zhejiang Province, China-312369 Responsibilities: Manufacturing, testing and stability studies, quality research, R&D, etc., for the API.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against the innovator product Keppra 100mg / mL Oral Solution (Levetiracetam 100mg / mL) manufactured by UCB Pharma Limited, UK.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Manufacturer: Shangyu Jingxin Pharmaceutical Co., Ltd. Manufacturing site and address: No. 31 Weisan Road, Hangzhou Bay Shangyu Economic and Technological Development Area, Zhejiang Province, China.		
API Lot No.			
Description of Pack (Container closure system)	Transparent and translucent clear oral solution filled in amber color glass bottle with plastic cap and sealing packed in specified unit carton along with a leaflet insert.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-GP-OSLP-22001	RD-GP-OSLP-22002	RD-GP-OSLP-22003
Batch Size	20 bottles	20 bottles	20 bottles
Manufacturing Date	03-10-2022	03-10-2022	03-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Dexstom 30mg and 60mg capsule", which was conducted on 21-09-2020 & 22-09-2020 and was presented in 297th meeting of Registration Board held on 12th to 15th January 2021.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate no. (ZJ20190095) issued dated 05-08-2019 and validity 04-08-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of DRAP attested invoice related to the procurement of API.

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

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Firm submitted preservative efficacy test report.
2.	Submit the analysis report/COA of excipients propylene glycol and glycerine which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-42/2023-QC dated 1st December, 2023.	Firm submitted the COA of propylene glycol and glycerine includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol.
3.	Justify for keeping the pH acceptance criteria different from that recommended by the USP monograph of "Levetiracetam oral solution".	Firm submitted the reply that "Lepsi Oral Solution was developed against attached reference of "Levetiracetam Oral Solution" from the USP 43, 2020. Later the pH specifications changed from 4.8-6.3 to 4.8-7 in recent monograph of "Levetiracetam Oral solution" new edition. After which the testing specifications have been changed according to updated monograph of USP Since the pH observed remains within the existing range, the increase in limit range doesn't impact the pH of the oral solution: Following documents are attached in support of the justifications. • Old USP Monograph • Updated Trial Testing Specifications • CoA of Lepsi Oral solution analysed against recent monograph
4.	Justify for not including the test of specified microorganism in the specification of drug product, since the test is recommended by the USP monograph of "Levetiracetam oral solution".	Firm replied that they included the test of specified microorganism in the specification of drug product.
5.	Justify the batch size against the number of units to complete stability studies.	Applicant has used R&D equipment for syrup manufacturing. One 100mL pack/bottle was used for testing at each time point during the stability studies and the batch size is sufficient for performing stability testing for at least 24 months.
6.	According to the additional section letter issued by the Licensing Division, syrup section (general) granted on 25-10-2023, while the trial batches were manufactured in September,2022. Please provide the information about the area/section in which trial batches were manufactured back in 2022,along with minimum handling	

	capacity of the equipment used in the formulation of trail batches.	

Decision: Approved. Registration letter will be issued upon submission of "batch manufacturing record" and "batch release data at initial time point" of newly manufactured trial batches with batch size sufficient enough to perform complete stability studies as per prescribed quality standards, till the claimed shelf life along with commitment to perform complete stability studies on newly manufactured trial batches

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**

269.	Name, address of Applicant / Marketing Authorization Holder	M/s. Genetics Pharmaceuticals (Pvt.) Ltd. Address: 539-A, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan
	Name, address of Manufacturing site.	M/s. Genetics Pharmaceuticals (Pvt.) Ltd. Address: 539-A, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted GMP certificate no.93/2022-DRAP(AD-5312766601) dated 06th June,2022.
	Evidence of approval of manufacturing facility	Firm submitted grant of additional section letter (new section) dated 25th October,2023 of Syrup section (General)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID no. D9S-7PH-7L3P Application no. 1572 dated 02-02-2024
	Details of fee submitted	Rs.75,000/- vide slip no. 82974246 dated 16-01-2024
	The proposed proprietary name / brand name	**GenLin 20mg/mL Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Oral Solution containing: Pregabalin … 20 mg.
	Pharmacotherapeutic Group of (API)	Gamma-aminobutyric acid analogs
	Pharmaceutical form of applied drug	Oral Solution
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lyrica 20 mg/ml® Oral Solution is Approved in USFDA.
	For generic drugs (me-too status)	NA

	Name and address of API manufacturer.	CTX LIFESCIENCES PVT. LIMITED Address of Manufacturing Facility : CTX Lifesciences Pvt. Ltd. Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230 Gujarat, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 72 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against the innovator product Lyrica Oral Solution 20 mg/ml of Pfizer, Inc.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA		
Manufacturer of API	CTX LIFESCIENCES PVT. LIMITED Address of Manufacturing Facility : CTX Lifesciences Pvt. Ltd. Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230 Gujarat, INDIA.	
API Lot No.	22PL000052.	
Description of Pack (Container closure system)	HDPE bottle with a white cap.	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	GN-L001.	GN-L002
Batch Size	2000 bottles	2000 bottles

Manufacturing Date	01/2023.	03-10-2022
No. of Batches	03	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Dexstom 30mg and 60mg capsule", which was conducted on 21-09-2020 & 22-09-2020 and was presented in 297th meeting of Registration Board held on 12th to 15th January 2021.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted copy of GMP Certificate of API manufacturer.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of commercial invoice without attested from DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firn
1.	Submit analytical method verification report of drug substance performed by the drug product manufacturer.	Firm submitted analytical method verification report of drug substance performed by the drug product manufacturer
2.	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Submitted
3.	Provide reference of claimed filled volume of innovator product mentioned in the pharmaceutical equivalence table i.e. 100ml, while the Label of innovator product available on the USFDA website specifies that the product available in 16 fl oz (473 ml) volume size.	Firm replied that "Our claimed filled volume is 120mL that is as per requirement in Pakistan and packaging material available in market. The filled volume does not affect the stability and efficacy of GenLin Oral Solution. And 120mL also enhance the patient compliance, convenience and cost effectiveness".
4.	Provide reference/rational of claimed filled volume of applied product.	
5.	Analytical method given in section 3.2.P.5.2 claimed that you have used BP complied reference standard for the analysis of drug product while the submitted COA of reference standard in section 3.2.P.6 is USP complied, clarification is required in this regard.	Firm replied that "Finished Product complies with the BP specifications, more over in case of finished product analysis BP reference standard was used for analysis of Drug Product".
6.	According to the innovator review report stability of innovator drug product has been performed at the ICH alternative storage conditions of 30°C ± 2°C (at 35% relative humidity, ± 5%), justify for not performing the stability of applied drug product at the alternative storage condition as per the ICH	Firm replied that "*The Recommended storage conditions for the reference product specify a temperature of 30ºC, which aligns with typical room temperature. However, there is no specific mention of humidity control within these conditions. Therefore, we have followed conventional storage practices without adjusting*

	guideline since the drug product packaged in HDPE bottles.	*humidity levels. According to international Council of Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)) guidelines, the High-Density Polyethylene (HDPE) container used for storing the Product is not considered a semipermeable container. This information is crucial in ensuring the proper storage and maintaining the product stability*." However, the review report of innovator product clearly stated that "The provided stability data support storage of the drug product for 24 months at or below the ICH alternative storage conditions of 30o C +/- 2o C/35% Relative Humidity (RH) +/- 5% and a 45 day use period for opened bottles when stored at or below 30o C +/- 2o C/35% RH +/- 5%"
7.	In-use stability studies of opened bottles are required to be submitted along with proposed in-use storage statement and in-use shelf-life.	Firm replied that the applied product is ready to use formulation and requirement of in-use stability is associated with the formulations which needs to be reconstituted/diluted before administration.
8.	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Submitted
9.	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as recommended by the ICH guidelines**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

270.	Name, address of Applicant / Marketing Authorization Holder	M/s. Shrooq Pharmaceuticals (Pvt.) LTD. 21-km Ferozpur Road, Lahore
	Name, address of Manufacturing site.	M/s. Shrooq Pharmaceuticals (Pvt.) LTD. 21-km Ferozpur Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted copy of GMP certification no. 12/2022-DRAP(AD-89400934157) dated 10-02-2022.
	Evidence of approval of manufacturing facility	Firm submitted copy of grant of additional section letter in which eye/ear/nose drop section granted to firm dated 20-01-2022.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Tracking ID no. JWU-5TM-A2E8 Application no. 732 dated 02-02-2024
	Details of fee submitted	Rs.30,000/- vide slip no. 2174454153 dated 05-09-2023
	The proposed proprietary name / brand name	**Lutica Nasal Spray 0.05% w/w**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	50mcg/spray of Fluticasone Propionate
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Pharmaceutical form of applied drug	Nasal Spray
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA, FLONASE ALLERGY RELIEF FLUTICASONE PROPIONATE 0.05MG/SPRAY (Each 100-mg spray delivers 50 mcg of fluticasone propionate).
	For generic drugs (me-too status)	Ticovate Nasal Spray (Each spray contains Fluticasone Propionate 50mcg) of M/s. Saffron Pharmaceuticals Pakistan (Pvt.) Ltd. (Reg.no. 060353)
	Name and address of API manufacturer.	M/s. Shankus Pharmaceuticals, Plot No 9,10,11 Milan Industrial Estate, Santej, Ta: Kalol,Gujarat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance (M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA) at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against the comparator product Ticovate Nasal Spray (Each spray contains Fluticasone Propionate 50mcg) of M/s. Saffron Pharmaceuticals Pakistan (Pvt.) Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA		
API Lot No.	FTP/922001		
Description of Pack (Container closure system)	Almost color hazy suspension, filled in a plastic bottle fitted with a meter dose atomizing pump packed in unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	83 Bottles	83 Bottles	83 Bottles
Manufacturing Date	11/2022	11/2022	11/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted copy of GMP Certificate of API manufacturer (M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of commercial invoice without attested from DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Section 1.6.5(a) specify that M/s. Shankus Pharmaceuticals, Plot No 9,10,11 Milan Industrial Estate, Santej, Ta: Kalol, Gujarat, India is the drug substance manufacturer, while the GMP certificate of M/s. Flax Laboratories (Pvt.) Limited Raigad, India has been submitted in section 1.6.5(b). Further,	Firm has not submitted the reply of this query.

	according to section 3.2.S.2.1 drug substance manufacturer is M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA, clarify the disparities observed regarding the drug substance manufacturer.	
2.	Submit specification and analytical procedure used for analysis of drug substance by drug product manufacturer.	Firm has not submitted the specification and analytical procedure of drug substance by drug product manufacturer.
3.	Mobile phase ratio used by drug product manufacturer during verification studies of assay method was different from the mobile phase ratio recommended by USP monograph of fluticasone propionate, justification is required in this regard.	Firm replied that "*As per general Monograph of BP, change in mobile phase allowed and our Mobile phase is within the limit"* However, the firm has submitted only the statement without any calculations with reference to the allowable adjustment limit of mobile phase.
4.	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Firm has not submitted the reply of this query.
5.	Justify for not performing all the quality test in accordance with BP monograph of fluticasone propionate nasal spray while establishing the pharmaceutical equivalence against the comparator product..	Firm has not submitted the reply of this query.
6.	Justify for not including the test of uniformity of delivered dose, test of number of deliveries per container and leak test as recommended by the BP monograph of fluticasone propionate nasal spray. Further, clarify the stated amount of assay test either it is amount actuation from the valve or otherwise.	Firm has not submitted the reply of this query.
7.	Justify for not adopting the analytical procedure of drug product in accordance with the BP monograph of fluticasone propionate nasal spray as evident from the submitted procedure in the relevant section.	Firm replied that "*As per general Monograph of BP, change in mobile phase allowed and our Mobile phase is within the limit"* However, the firm has submitted only the statement without any calculations with reference to the allowable adjustment limit of mobile phase.
8.	Please specify the details of spray configuration/no. of actuation with reference to the filled volume.	Firm replied that 120 Spray = 14ml+0.2ml.
9.	Justify for not performing the stability of drug product at alternate condition recommended in ICH guidelines for drug product packaged in plastic containers.	Firm has not submitted the reply of this query.
10	Justify for not including all the quality test recommended by the BP monograph of fluticasone propionate nasal spray while performing the stability of drug product.	Firm has not submitted the reply of this query.
11	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of	Firm has submitted procurement document of API without attested by AD (I&E) DRAP

	drug substance used in manufacturing of these batches of drug product.	
12	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted.

Decision: Deferred for submission of following shortcomings:

- **Section 1.6.5(a) specify that M/s. Shankus Pharmaceuticals, Plot No 9,10,11 Milan Industrial Estate, Santej, Ta: Kalol, Gujarat, India is the drug substance manufacturer, while the GMP certificate of M/s. Flax Laboratories (Pvt.) Limited Raigad, India has been submitted in section 1.6.5(b). Further, according to section 3.2.S.2.1 drug substance manufacturer is M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA, clarify the disparities observed regarding the drug substance manufacturer.**
- **Submit specification and analytical procedure used for analysis of drug substance by drug product manufacturer.**
- **Justify the change in mobile phase ratio while performing the assay of drug substance drug product in the light of allowable adjustment limit of mobile phase as mentioned in the general chapters of USP**.
- **Justify for not performing all the quality test in accordance with BP monograph of fluticasone propionate nasal spray while establishing the pharmaceutical equivalence against the comparator product.**
- **Justify for not including the test of uniformity of delivered dose, test of number of deliveries per container and leak test as recommended by the BP monograph of fluticasone propionate nasal spray. Further, clarify the stated amount of assay test either it is amount actuation from the valve or otherwise.**
- **Justify for not performing the stability of drug product at alternate condition recommended in ICH guidelines for drug product packaged in plastic containers.**
- **Justify for not including all the quality test recommended by the BP monograph of fluticasone propionate nasal spray while performing the stability of drug product.**

271.	Name, address of Applicant / Marketing Authorization Holder	M/s. Shrooq Pharmaceuticals (Pvt.) LTD. 21-km Ferozpur Road, Lahore
	Name, address of Manufacturing site.	M/s. Shrooq Pharmaceuticals (Pvt.) LTD. 21-km Ferozpur Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted copy of GMP certification no. 12/2022-DRAP(AD-89400934157) dated 10-02-2022.
	Evidence of approval of manufacturing facility	Firm submitted copy of grant of additional section letter in which eye/ear/nose drop section granted to firm dated 20-01-2022.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID no. A9Z-QNA-BS5Q Application no. 604 dated 02-02-2024
	Details of fee submitted	Rs.30,000/- vide slip no. 45995881099 dated 05-09-2023
	The proposed proprietary name / brand name	Medison Nasal Spray 0.05% w/w
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	50mcg/spray of Mometasone Furoate
	Pharmacotherapeutic Group of (API)	Corticosteroid

	Pharmaceutical form of applied drug	Nasal Spray
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA, NASONEX 24HR ALLERGY MOMETASONE FUROATE 0.05MG/SPRAY
	For generic drugs (me-too status)	MMS Nasal Spray 0.05% w/w (Each spray contains Mometasone Furoate 50mcg) of Remington Pharmaceuticals Industries (Pvt.) Ltd. (Reg.no. 076820)
	Name and address of API manufacturer.	M/s. SWATI SPENTOSE PRIVATE LIMITED A1/2111, Phase III, G.I.D.C, Vapi, Gujarat – 396 195, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance (M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA) at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against the comparator product MMS Nasal Spray 0.05% w/w of Remington Pharmaceuticals (Pvt.) Ltd. Lahore.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA
API Lot No.	FTP/922001
Description of Pack (Container closure system)	Almost color hazy suspension, filled in a plastic bottle fitted with a meter dose atomizing pump packed in unit carton along with leaflet.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	83 Bottles	83 Bottles	83 Bottles
Manufacturing Date	11/2022	11/2022	11/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted copy of GMP Certificate of API manufacturer (M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of commercial invoice without attested from DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Section 1.6.5(a) specify that M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA is the drug substance manufacturer, while the GMP certificate of M/s. Flax Laboratories (Pvt.) Limited Raigad, India has been submitted in section 1.6.5(b).Clarify for submitting the GMP certificate of M/s. FLAX Laboratories instead of M/s. Sawati Spentose Pvt. Ltd.	Firm has not submitted the reply of this query.
2.	Submit specification and analytical procedure used for analysis of drug substance by drug product manufacturer.	Firm has not submitted the specification and analytical procedure of drug substance by drug product manufacturer.
3.	Justify for performing verification studies on assay method different from the assay procedure recommended by the	Firm replied that "Method is as per BP not USP". However the drug substance manufacturer complied USP specification for drug substance as per the submitted documents in the relevant section.

	USP monograph of Mometasone Furoate.	
4.	Justify for not including the test of optical rotation while quality analysis of drug substance by drug product manufacturer.	Firm submitted the revised quality analysis report of drug substance in which test of optical rotation is included.
5.	Submit the amended label claim specifying the delivered volume containing the quantity of mometasone Furoate	Firm replied "*Each spray = 0.1ml Mometasone Furoate= 50mcg".* However, the label claim of innovator product is "*Each actuation of the pump delivers a metered spray containing 100 mcg or 100 microliter of aqueous suspension of mometasone furoate monohydrate equivalent to 50 mcg (0.05% w/w) mometasone furoate calculated on the anhydrous basis."*
6.	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Firm has not submitted the reply of this query.
7.	Submit the analysis report/COA of excipients glycerine which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-6/2024-QC dated 30th January,2024.	Firm has not submitted the reply of this query.
8.	Justify for not performing all the quality test in accordance with BP monograph of Mometasone Furoate aqueous nasal spray while establishing the pharmaceutical equivalence against the comparator product.	Firm has not submitted the reply of this query.
9.	Provide the reference of label claim mentioned in the pharmaceutical equivalence table	Firm has not submitted the reply of this query.
10	Justify for not including the test of uniformity of delivered dose, test of number of deliveries per container and leak test as recommended by the BP monograph of Mometasone Furoate aqueous nasal spray. Further, clarify the stated amount of assay test either it is amount actuation from the valve or otherwise.	Firm has not submitted the reply of this query.
11	Justify for not adopting the analytical procedure of drug product in accordance with the BP monograph of Mometasone Furoate aqueous nasal spray as evident from the submitted procedure in the relevant section.	Firm has not submitted the reply of this query.
12	Please specify the details of spray configuration/no. of actuation with reference to the filled volume.	
13	Justify for not performing the stability of drug product at alternate condition recommended in ICH guidelines for drug product packaged in plastic containers.	Firm has not submitted the reply of this query.

14	Justify for not including all the quality test recommended by the BP monograph of Mometasone Furoate aqueous nasal spray while performing the stability of drug product.	Firm has not submitted the reply of this query.
15	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm has submitted procurement document of API without attested by AD (I&E) DRAP.
16	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted BMR reflects that 14ml filled in each bottle Label claim *Each spray contains: Mometasone Furoate…50mcg (Each bottle contains 120 sprays).*

Decision: Deferred for submission of following shortcomings:

- **Section 1.6.5(a) specify that M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA is the drug substance manufacturer, while the GMP certificate of M/s. Flax Laboratories (Pvt.) Limited Raigad, India has been submitted in section 1.6.5(b). Clarify for submitting the GMP certificate of M/s. FLAX Laboratories instead of M/s. Sawati Spentose Pvt. Ltd.**
- **Submit specification and analytical procedure used for analysis of drug substance by drug product manufacturer.**
- **Justify for adopting the BP specification for USP complied drug substance, since the drug substance manufacturer claimed USP specification for drug substance.**
- **Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.**
- **Submit the analysis report/COA of excipients glycerine which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-6/2024-QC dated 30th January,2024.**
- **Justify for not performing all the quality test in accordance with BP monograph of Mometasone Furoate aqueous nasal spray while establishing the pharmaceutical equivalence against the comparator product.**
- **Provide the reference of label claim mentioned in the pharmaceutical equivalence table.**
- **Justify for not including the test of uniformity of delivered dose, test of number of deliveries per container and leak test as recommended by the BP monograph of Mometasone Furoate aqueous nasal spray. Further, clarify the stated amount of assay test either it is amount actuation from the valve or otherwise.**
- **Justify for not adopting the analytical procedure of drug product in accordance with the BP monograph of Mometasone Furoate aqueous nasal spray as evident from the submitted procedure in the relevant section.**
- **Justify for not performing the stability of drug product at alternate condition recommended in ICH guidelines for drug product packaged in plastic containers.**
- **Justify for not including all the quality test recommended by the BP monograph of Mometasone Furoate aqueous nasal spray while performing the stability of drug product.**

NEW DML APPLICATION RECEIVED ON FORM 5-F:

272.	Name, address of Applicant / Marketing Authorization Holder	M/s. Qadir Pharmaceuticals Address: Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Name, address of Manufacturing site.	M/s. Qadir Pharmaceuticals Address: Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted copy of DML issue dated 13-09-2021.
	Evidence of approval of manufacturing facility	Firm submitted copy of issuance of DML Letter dated 17-09-2021 with the list of approved section including tablet general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID no. V5A-8QN-U986 Application no. 1074 dated 02-02-2024
	Details of fee submitted	Rs.30,000/- vide slip no. 256673461543 dated 18-12-2023
	The proposed proprietary name / brand name	**SITAQAD 50mg/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Metformin Hydrochloride …… 1000mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin …….50mg
	Pharmacotherapeutic Group of (API)	For the treatment of Diabetes mellitus Type II/Hypoglycemic Agents/Blood sugar lowering agents
	Pharmaceutical form of applied drug	Film-coated tablets
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	EMA (emc) Janumet tablets
	For generic drugs (me-too status)	TreviaMet 50mg/1000mg of M/s. Getz Pharma Pakistan (PVT) Ltd of Reg.no. 055444.
	Name and address of API manufacturer.	Metformin Hydrochloride: M/s. AARTI DRUGS LTD MANUFACTURING FACILITY Plot No. G– 60, M.I.D.C. Tarapur, Tal. - Palghar, Dist.: Thane - 401 506, Maharashtra. INDIA. Sitagliptin Phosphate Monohydrate Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance (sitagliptin phosphate) at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Firm has submitted stability study data of 3 batches of drug substance (Metformin Hydrochloride) at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against the comparator product Sitaglu Met 50mg+1000mg Tablets of M/s.Hilton Pharma (PVT.) Ltd. Further, submitted comparative dissolution against the same above mentioned comparator product in all three medias.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Metformin Hydrochloride: M/s. AARTI DRUGS LTD MANUFACTURING FACILITY Plot No. G– 60, M.I.D.C. Tarapur, Tal. - Palghar, Dist.: Thane - 401 506, Maharashtra. INDIA. Sitagliptin Phosphate Monohydrate: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China		
API Lot No.	L-D05-CP11422001 MEF/12031196		
Description of Pack (Container closure system)	A white color oblong shape, film coated tablet, Score on one side in Alu-Alu Blister packs in unit carton with leaflet		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTR040	TTR041	TTR042
Batch Size	600 tablets	600 tablets	600 tablets
Manufacturing Date	04/2023.	04/2023.	04/2023.
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate of both API manufacturers.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of commercial invoice without attested from DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings	Reply
1.	3.2.S.4.1-3.2.S.4.2	Submit specification and analytical procedure used for analysis of both drug substances by drug product manufacturer.	Firm submitted the specification and analytical procedure of both drug substance.
2.	3.2.S.4.1	Justify for using in-house complied drug substance (sitagliptin phosphate) for the manufacturing of drug product when the official monograph of sitagliptin phosphate is available in the USP.	Firm replied that This is a mistake from the procurement department though the parameters are similar to USP still we undertake that for commercial product manufacturing we will use USP monograph API.
3.	3.2.S.4.3	Submit analytical method verification report of both drug substance performed by the drug product manufacturer.	Firm submitted the same validation/verification report of drug substance as submitted for drug product.
4.	3.2.S.4.4	Submit batch analysis report of both drug substance by drug product manufacturer.	Submitted
5.	3.2.S.7	Stability data of sitagliptin phosphate specified that the drug substance complied USP specification while the other sections of drug substance part claimed that the in-house complied sitagliptin phosphate has been used in the manufacturing of drug product.	Firm replied that "The accelerated stability study of sitagliptin phosphate specified that the drug substance complied USP is in API manufacturer DMF, we have communicated the matter to the API manufacturer to address the subject, and we will communicate to the DRAP as will received their reply".
6.	3.2.P.5.1	Specify the acceptance criteria of dissolution test in term of Q value, since the BP monograph of applied product recommends the acceptance limit of dissolution test in terms of Q value.	Firm replied that "The acceptance criteria of dissolution test in term of Q value are 80% in the BP monograph of applied product". Dissolution acceptance limit need to be changed in accordance with BP monograph.
7.	3.2.P.5.2	Justify for not adopting the same assay procedure as recommended by the BP monograph of Metformin and Sitagliptin Tablets, since the submitted method is different from the procedure given in official monograph of BP.	Firm replied that "The method adopted in the assay was that for dissolution of tablet due to isocratic mode and give good results for both drug substances. We undertake to use gradient method in future for the assay of combination tablets" Firm has not adopted BP specification for the applied product, since the assay procedure acquired by the firm is not in accordance with BP monograph.
8.	3.2.P.5.3	Assay procedure verified is not in accordance with BP Monograph ,justify	Firm replied that "Sir please consider it valid. The same BP dissolution method in isocratic mode was

		how the applied product complied BP specification.	used for the method verification of both substances and is well within the range of acceptance criteria". Firm has not adopted BP specification for the applied product, since the assay procedure acquired by the firm is not in accordance with BP monograph.
9.	3.2.P.8	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted Form-6 of both drug substance.
10	2.3.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted.

Decision: Deferred for submission of following shortcomings:

- **Submit PKR 7500/- pre-registration variation fee for revision of specification, prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023.**
- **Submit analytical method verification report of both drug substances performed by the drug product manufacturer, since in the reply you have submitted the same verification report as submitted for drug product.**
- **Clarify the ambiguity related to the specification of drug substance, since the documents supplied by the drug substance manufacturer shows disparity in the specification claim of drug substance in their various sections.**
- **Revise the dissolution acceptance limit in accordance to the BP Monograph of applied product.**
- **Revise the assay procedure of applied product in accordance with the BP Monograph of "Metformin and Sitagliptin Tablet" and accordingly submit the performance report of next time point of long term stability studies.**
- **Submit analytical verification report of drug product, which is performed in accordance with the "Metformin and Sitagliptin Tablet"**

273.	Name, address of Applicant / Marketing Authorization Holder	M/s. Qadir Pharmaceuticals Address: Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Name, address of Manufacturing site.	M/s. Qadir Pharmaceuticals Address: Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted copy of DML issue dated 13-09-2021.
	Evidence of approval of manufacturing facility	Firm submitted copy of issuance of DML Letter dated 17-09-2021 with the list of approved section including tablet general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID no. 82V-HAH-4GEN Application no. 1044 dated 02-02-2024
	Details of fee submitted	Rs.30,000/- vide slip no. 914933883933 dated 18-12-2023

	The proposed proprietary name / brand name	**SITAQAD 50mg/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Metformin Hydrochloride……500mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin …….50mg
	Pharmacotherapeutic Group of (API)	For the treatment of Diabetes mellitus Type II/Hypoglycemic Agents/Blood sugar lowering agents
	Pharmaceutical form of applied drug	Film-coated tablets
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	EMA (emc) Janumet tablets
	For generic drugs (me-too status)	TreviaMet 50mg/500mg of M/s. Getz Pharma Pakistan (PVT) Ltd of Reg.no. 055443.
	Name and address of API manufacturer.	Metformin Hydrochloride: M/s. AARTI DRUGS LTD MANUFACTURING FACILITY Plot No. G– 60, M.I.D.C. Tarapur, Tal. - Palghar, Dist.: Thane - 401 506, Maharashtra. INDIA. Sitagliptin Phosphate Monohydrate Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance (sitagliptin phosphate) at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Firm has submitted stability study data of 3 batches of drug substance (Metformin Hydrochloride) at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference

		standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against the comparator product Sitaglu Met 50/500mg of Hilton Pharma (PVT) Ltd. Further, submitted comparative dissolution against the same above mentioned comparator product in all three medias.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Metformin Hydrochloride: M/s. AARTI DRUGS LTD MANUFACTURING FACILITY Plot No. G– 60, M.I.D.C. Tarapur, Tal. - Palghar, Dist.: Thane - 401 506, Maharashtra. INDIA. Sitagliptin Phosphate Monohydrate: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China		
API Lot No.	L-D05-CP11422001 MEF/12031196		
Description of Pack (Container closure system)	A white color oblong shape, film coated tablet, Score on one side in Alu-Alu Blister packs in unit carton with leaflet		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTR037	TTR038	TTR039
Batch Size	600 tablets	600 tablets	600 tablets
Manufacturing Date	04/2023.	04/2023.	04/2023.
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate of both API manufacturers.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of commercial invoice without attested from DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings	Reply

1.	3.2.S.4.1-3.2.S.4.2	Submit specification and analytical procedure used for analysis of both drug substances by drug product manufacturer.	Firm submitted the specification and analytical procedure of both drug substance.
2.	3.2.S.4.1	Justify for using in-house complied drug substance (sitagliptin phosphate) for the manufacturing of drug product when the official monograph of sitagliptin phosphate is available in the USP.	Firm replied that This is a mistake from the procurement department though the parameters are similar to USP still we undertake that for commercial product manufacturing we will use USP monograph API.
3.	3.2.S.4.3	Submit analytical method verification report of both drug substance performed by the drug product manufacturer.	Firm submitted the same validation/verification report of drug substance as submitted for drug product.
4.	3.2.S.4.4	Submit batch analysis report of both drug substance by drug product manufacturer.	Submitted
5.	3.2.S.7	Stability data of sitagliptin phosphate specified that the drug substance complied USP specification while the other sections of drug substance part claimed that the in-house complied sitagliptin phosphate has been used in the manufacturing of drug product.	Firm replied that "The accelerated stability study of sitagliptin phosphate specified that the drug substance complied USP is in API manufacturer DMF, we have communicated the matter to the API manufacturer to address the subject, and we will communicate to the DRAP as will received their reply".
6.	3.2.P.5.1	Specify the acceptance criteria of dissolution test in term of Q value, since the BP monograph of applied product recommends the acceptance limit of dissolution test in terms of Q value.	Firm replied that "The acceptance criteria of dissolution test in term of Q value are 80% in the BP monograph of applied product". Dissolution acceptance limit need to be changed in accordance with BP monograph.
7.	3.2.P.5.2	Justify for not adopting the same assay procedure as recommended by the BP monograph of Metformin and Sitagliptin Tablets, since the submitted method is different from the procedure given in official monograph of BP.	Firm replied that "The method adopted in the assay was that for dissolution of tablet due to isocratic mode and give good results for both drug substances. We undertake to use gradient method in future for the assay of combination tablets" Firm has not adopted BP specification for the applied product, since the assay procedure acquired by the firm is not in accordance with BP monograph.
8.	3.2.P.5.3	Assay procedure verified is not in accordance with BP Monograph ,justify how the applied product complied BP specification.	Firm replied that "Sir please consider it valid. The same BP dissolution method in isocratic mode was used for the method verification of both substances and is well within the range of acceptance criteria". Firm has not adopted BP specification for the applied product, since the assay procedure acquired by the firm is not in accordance with BP monograph.
9.	3.2.P.8	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted Form-6 of both drug substance.
10	2.3.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted.
Decision: Deferred for submission of following shortcomings:			

- **Submit PKR 7500/- pre-registration variation fee for revision of specification, prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023.**
- **Submit analytical method verification report of both drug substances performed by the drug product manufacturer, since in the reply you have submitted the same verification report as submitted for drug product.**
- **Clarify the ambiguity related to the specification of drug substance, since the documents supplied by the drug substance manufacturer shows disparity in the specification claim of drug substance in their various sections.**
- **Revise the dissolution acceptance limit in accordance to the BP Monograph of applied product.**
- **Revise the assay procedure of applied product in accordance with the BP Monograph of "Metformin and Sitagliptin Tablet" and accordingly submit the performance report of next time point of long term stability studies.**
- **Submit analytical verification report of drug product, which is performed in accordance with the "Metformin and Sitagliptin Tablet"**

Agenda of Evaluator PEC-XX

Registration applications of New section (Human):

274.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate dated 20.04.2023 based on inspection dated 03.04.2023 valid for 2 years.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 07.06.2022 specifying Dry Powder Suspension (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No: 15827 dated 22.06.2023
	Details of fee submitted	PKR 30,000/- Dated 13-06-2023
	The proposed proprietary name / brand name	**Cefaclor 125mg/5ml Powder for oral suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cefaclor monohydrate eq. to Cefaclor …….125mg
	Pharmacotherapeutic Group of (API)	Cephalosporin (Antibacterial)
	Pharmaceutical form of applied drug	Dry Powder for oral Suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 30ml, 1 x 60ml As per SRO

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Cavalor 125mg/5ml powder for oral suspension M/s Barrett Hodgson Pakistan (Pvt) Ltd (Reg No 030975)
	Name and address of API manufacturer.	China Union Chempharma (SuZhou) Co., Ltd No. 6 Jinzi Road, Lili Town , Wujiang District, Suzhou city, Jiangsu Province China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 18 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (KL200403, KL200404, KL200405)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Cefalor 125mg/5ml powder for oral suspension, Quality parameters such as identification, pH and Assay were compared.
	Analytical method validation study of product	Firm has submitted analytical method verification study reports for drug substance and drug product.

STABILITY STUDY DATA	
Manufacturer of API	China Union Chempharma (SuZhou) Co., Ltd No. 6 Jinzi Road, Lili Town , Wujiang District, Suzhou city, Jiangsu Province China
API Lot No.	201211101
Description of Pack (Container closure system)	Amber glass bottle
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	TJI001	TJI002	TJI003
Batch Size	325 Bottles	325 Bottles	325 Bottles
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	28-08-2022	29-08-2022	30-08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided GMP certificate No JS20160635 issued by China Food and Drug Administration date 01.03.2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided loan letter dated 11.08.2022 from M/s Shawan Pharmaceuticals, regarding borrowing API (Cefaclor monohydrate micronized/compacted). Firm has provided clearance certificate from I&E dated 04 April 2022 wherein 25kg Cefaclor monohydrate (micronized) Batch No 201211101 was mentioned
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1	Valid approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Firm has provided Pharmaceutical Product License No Su20160183 issued by Jiangsu Food and Drug Administration dated 15.03.2021 valid till 21.10.2025.	Complied
2	Regulatory status of diluent (WFI) in Pakistan is required with details of manufacturer and Registration No.	We are not providing any diluent with suspension as mentioned in label of pack that use boil water for reconstitution	Clarified
3	Provide details of container closure system (Glass bottle Type) and submit suitability testing as per pharmacopeia.	CoA of glass bottle has been provided	Glass type, specification/ quality tests (as per pharmacopeia) has not been provided.

4	Provide details of comparator product (Manufacturer, Batch No and Exp date) under pharmaceutical equivalence study.	Cefalor 125mg/5ml powder for oral suspension Batch No R220363 Exp date: 12-23	
5	Provide details regarding volume of diluent to be used for reconstitution to achieve label claim 250mg/5ml along with weight/ml calculation with reference to innovator's product	40ml of diluent to be used for reconstitution to achieve label claim 125mg/5ml and 250mg/5ml	Pack size/ total volume (per pack) to be clarified. Since comparator product's pack size is 60ml.
6	Provide Drug-excipient compatibility study with Aerosil , sodium benzoate, sodium citrate, citric acid anhydrous, Simethicone (being qualitatively different from innovator's/reference product).	Provided	API Cefaclor monohydrate (micronized) found compatible with Aerosil , sodium benzoate, sodium citrate, citric acid anhydrous, Simethicone
7	In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products en.pdf)	In use stability data (reconstituted form) provided for 14 days.	Stability Data of trial batch is provided performed at initial time point.

Decision: Approved. Approved. Registration letter will be issued upon submission of following:

i. **In-use stability data (reconstituted form) at the recent most time point of stability studies.**
ii. **Proposed fill volume after reconstitution.**
iii. **Type of glass container**

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

275.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate dated 20.04.2023 based on inspection dated 03.04.2023 valid for 2 years.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 07.06.2022 specifying Dry Powder Suspension (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No: 15828 dated 22.06.2023
	Details of fee submitted	PKR 30,000/- Dated 13-06-2023
	The proposed proprietary name / brand name	**Cefaclor 250mg/5ml Powder for oral suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cefaclor monohydrate eq. to Cefaclor ……250mg
	Pharmacotherapeutic Group of (API)	Cephalosporin (Antibacterial)
	Pharmaceutical form of applied drug	Dry Powder for oral Suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 30ml, 1 x 60ml As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Cavalor 250mg/5ml powder for oral suspension M/s Barrett Hodgson Pakistan (Pvt) Ltd (Reg No 030976)
	Name and address of API manufacturer.	China Union Chempharma (SuZhou) Co., Ltd No. 6 Jinzi Road, Lili Town , Wujiang District, Suzhou city, Jiangsu Province China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 18 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and

		justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Cefalor 250mg/5ml powder for oral suspension, Quality parameters such as identification, pH and Assay were compared.
	Analytical method validation study of product	Firm has submitted analytical method verification study reports for drug substance and drug product.

STABILITY STUDY DATA			
Manufacturer of API	China Union Chempharma (SuZhou) Co., Ltd No. 6 Jinzi Road, Lili Town , Wujiang District, Suzhou city, Jiangsu Province China		
API Lot No.	201211101		
Description of Pack (Container closure system)	Amber glass bottle		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	TJJ001	TJJ002	TJJ003
Batch Size	325 Bottles	325 Bottles	325 Bottles
Manufacturing Date	09-2022	08-2022	09-2022
Date of Initiation	01-09-2022	02-09-2022	03-09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided GMP certificate No JS20160635 issued by China Food and Drug Administration date 01.03.2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided loan letter dated 11.08.2022 from M/s Shawan Pharmaceuticals, regarding borrowing API (Cefaclor monohydrate micronized/compacted). Firm has provided clearance certificate from I&E dated 04 April 2022 wherein 25kg Cefaclor monohydrate (micronized) Batch No 201211101 was mentioned
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr. #	Observations	Reply	Remarks
1	Valid approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Firm has provided Pharmaceutical Product License No Su20160183 issued by Jiangsu Food and Drug Administration dated 15.03.2021 valid till 21.10.2025.	Complied
2	Regulatory status of diluent (WFI) in Pakistan is required with details of manufacturer and Registration No.	We are not providing any diluent with suspension as mentioned in label of pack that use boil water for reconstitution	Clarified
3	Provide details of container closure system (Glass bottle Type) and submit suitability testing as per pharmacopeia.	CoA of glass bottle has been provided	Glass type, specification/ quality tests (as per pharmacopeia) has not been provided.
4	Provide details of comparator product (Manufacturer, Batch No and Exp date) under pharmaceutical equivalence study.	Cefalor 250mg/5ml powder for oral suspension Batch No R220391 Exp date: 12-23	
5	Provide details regarding volume of diluent to be used for reconstitution to achieve label claim 250mg/5ml along with weight/ml calculation with reference to innovator's product	40ml of diluent to be used for reconstitution to achieve label claim 125mg/5ml and 250mg/5ml	Pack size/ total volume (per pack) to be clarified. Since comparator product's pack size is 60ml.
6	Provide Drug-excipient compatibility study with Aerosil , sodium benzoate, sodium citrate, citric acid anhydrous, Simethicone (being qualitatively different from innovator's/reference product).	Provided	API Cefaclor monohydrate (micronized) found compatible with Aerosil , sodium benzoate, sodium citrate, citric acid anhydrous, Simethicone
7	In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products en.pdf)	In use stability data (reconstituted form) provided for 14 days.	Stability Data of trial batch is provided performed at initial time point.

Decision: Approved. Registration letter will be issued upon submission of following:

iv. In-use stability data (reconstituted form) at the recent most time point of stability studies.

v. Proposed fill volume after reconstitution.

vi. Type of glass container.

	• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
276.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate dated 20.04.2023 based on inspection dated 03.04.2023 valid for 2 years.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 07.06.2022 specifying Capsule (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No: 17949 dated 17.07.2023
	Details of fee submitted	PKR 30,000/- Dated 13-06-2023
	The proposed proprietary name / brand name	Cefaclor 500mg capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefaclor monohydrate eq. to Cefaclor …….500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin (Antibacterial)
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	In house specification
	Proposed Pack size	2x6's, 1x10's, 2x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Slate 500mg capsule (Reg No 047029) M/s Healthtek Pvt Ltd
	Name and address of API manufacturer.	China Union Chempharma (SuZhou) Co., Ltd No. 6 Jinzi Road, Lili Town , Wujiang District, Suzhou city, Jiangsu Province China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls,

		specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 18 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (KL200403, KL200404, KL200405)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Slate 500mg capsule (M/s Healthtek Pvt Ltd) Quality parameters such as identification, dissolution and Assay were compared.
	Analytical method validation study of product	Firm has submitted analytical method verification study reports for drug substance and drug product.

STABILITY STUDY DATA			
Manufacturer of API	China Union Chempharma (SuZhou) Co., Ltd No. 6 Jinzi Road, Lili Town , Wujiang District, Suzhou city, Jiangsu Province China		
API Lot No.	2012111003		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	TJH001	TJH002	TJH003
Batch Size	2000 capsules	2000 capsules	2000 capsules
Manufacturing Date	09-2022	08-2022	08-2022
Date of Initiation	01-09-2022	02-09-2022	03-09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided GMP certificate No JS20160635 issued by China Food and Drug Administration date 01.03.2019 valid till 25.12.2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided loan letter dated 11.08.2022 from M/s Shawan Pharmaceuticals, regarding borrowing API (Cefaclor monohydrate micronized/compacted). Firm has provided clearance certificate from I&E dated 04 April 2022 wherein 25kg Cefaclor monohydrate (compacted) Batch No 201211103 was mentioned
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1	Valid approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Firm has provided Pharmaceutical Product License No Su20160183 issued by Jiangsu Food and Drug Administration dated 15.03.2021 valid till 21.10.2025.	Complied
2	Provide details of comparator product (Manufacturer, Batch No and Exp date) under pharmaceutical equivalence study.	Slate 500mg capsule (M/s Healthtek Pvt Ltd) Batch No 002G Exp date: 03-2023	
3	Provide Drug-excipient compatibility study with Dimethicone Starch (being qualitatively different from innovator's formulation).	Provided	API Cefaclor monohydrate (compacted) found compatible with Dimethicone Starch.
4	Finished product specification need to be clarified. since specification mentioned on Form5F as "in house" while applied	Finished product specification is USP and we perform all tests as per USP. There is a typographic error in mentioning specification on Form5F	Fee of Rs 7500/- to be submitted on account of pre-registration variation.

	formulation is available in USP.		

Decision: Registration Board approved the application. Before issuance of registration letter firm will submit fee of Rs 7500/- on account of pre-registration variation (product specification).

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

277.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate dated 20.04.2023 based on inspection dated 03.04.2023 valid for 2 years.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 07.06.2022 specifying Dry Powder suspension (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No: 13383 dated 30.05.2023
	Details of fee submitted	PKR 30,000/- Dated 17-05-2023
	The proposed proprietary name / brand name	**Cefaxil 125mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cefadroxil monohydrate eq. to Cefadroxil ……125mg
	Pharmacotherapeutic Group of (API)	Cephalosporin (Antibacterial)
	Pharmaceutical form of applied drug	Dry Powder for oral suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Duricef 125mg/5ml powder for oral suspension M/s GSK (Reg No 008014)
	Name and address of API manufacturer.	ACS Dobfar S.P.A Via Marzabotto, 1,7/9-20871 Vimercate (MB)

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (55021500223, 55021500233, 55021500243)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Duricef 125mg/5ml powder for oral suspension by GSK, Quality parameters such as identification, pH, Dissolution and Assay were compared. CDP has been performed against the same brand that is Duricef 125mg/5ml powder for oral suspension by GSK in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range
	Analytical method validation study of product	Firm has submitted analytical method verification study reports for drug substance and drug product.

STABILITY STUDY DATA	
Manufacturer of API	ACS Dobfar S.P.A Via Marzabotto, 1,7/9-20871 Vimercate (MB
API Lot No.	00169
Description of Pack (Container closure system)	Glass bottle
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	TJE001	TJE002	TJE002
Batch Size	200 bottles	200 bottles	200 bottles
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	24-07-2022	25-07-2022	26-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No IT-API/51/H/2019 based on inspection dated 26/10/2018 issued by AIFA valid till 42 months from the date of inspection
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided loan letter dated 02.07.2022 from M/s Medisave Pharmaceuticals, regarding borrowing API (cefadroxil monohydrate)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr. #	Observations	Reply	Remarks
1	Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Firm has provided copy of GMP certificate No IT-API/51/H/2023 based on inspection dated 26/05/2023 issued by AIFA valid till 42 months from the date of inspection	Complied
2	Regulatory status of diluent (WFI) in Pakistan is required with details of manufacturer and Registration No.	We are not providing any diluent with suspension as mentioned in label of pack that use boil water for reconstitution	Clarified
3	Provide details of container closure system (Glass bottle Type) and submit suitability testing as per pharmacopeia.	CoA of glass bottle has been provided	Glass type, specification/ quality tests (as per pharmacopeia) has not been provided.

4	Provide details of comparator product (Batch No and Exp date) under pharmaceutical equivalence study.	Duricef 125mg/5ml powder for oral suspension by GSK Batch No: 7D2J Exp date: 11-24	
5	Provide details regarding volume of diluent to be used for reconstitution to achieve label claim 125mg/5ml along with weight/ml calculation with reference to innovator's product	60ml of diluent to be used for reconstitution to achieve label claim 125mg/5ml and 250mg/5ml	Pack size/ total volume (per pack) to be clarified. Since comparator product's pack size is 90ml.
6	Provide commercial invoice of API (by Medisave pharmaceuticals) and clearance by I&E DRAP	Commercial invoice of Cefadroxil (micronized) batch No 00169 cleared by I&E DRAP dated 29.01.2020 in the name of M/s Medisave Pharmaceuticals.	Complied
7	In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products en.pdf)	In use stability data (reconstituted form) provided for 14 days.	Stability Data of trial batch is provided performed at initial time point.

Decision: Approved. Approved. Registration letter will be issued upon submission of following:

i. **In-use stability data (reconstituted form) at the recent most time point of stability studies.**
ii. **Proposed fill volume after reconstitution.**
iii. **Type of glass container.**

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

278.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate dated 20.04.2023 based on inspection dated 03.04.2023 valid for 2 years.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 07.06.2022 specifying Dry Powder suspension (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No: 13384 dated 30.05.2023
	Details of fee submitted	PKR 30,000/- Dated 17-05-2023
	The proposed proprietary name / brand name	**Cefaxil 250mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cefadroxil monohydrate eq. to Cefadroxil ……250mg
	Pharmacotherapeutic Group of (API)	Cephalosporin (Antibacterial)
	Pharmaceutical form of applied drug	Dry Powder for oral suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Duricef 250mg/5ml powder for oral suspension M/s GSK (Reg No 010057)
	Name and address of API manufacturer.	ACS Dobfar S.P.A Via Marzabotto, 1,7/9-20871 Vimercate (MB)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (55021500223, 55021500233, 55021500243)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and

		justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Duricef 250mg/5ml powder for oral suspension by GSK, Quality parameters such as identification, pH, Dissolution and Assay were compared. CDP has been performed against the same brand that is Duricef 250mg/5ml powder for oral suspension by GSK in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range
	Analytical method validation study of product	Firm has submitted analytical method verification study reports for drug substance and drug product.

STABILITY STUDY DATA			
Manufacturer of API	ACS Dobfar S.P.A Via Marzabotto, 1,7/9-20871 Vimercate (MB		
API Lot No.	00169		
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	TJF001	TJF002	TJF003
Batch Size	200 bottles	200 bottles	200 bottles
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	27-07-2022	28-07-2022	29-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No IT-API/51/H/2019 based on inspection dated 26/10/2018 issued by AIFA valid till 42 months from the date of inspection
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided loan letter dated 02.07.2022 from M/s Medisave Pharmaceuticals, regarding borrowing API (cefadroxil monohydrate)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr. #	Observations	Reply	Remarks
	Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Firm has provided copy of GMP certificate No IT-API/51/H/2023 based on inspection dated 26/05/2023 issued by AIFA valid till 42 months from the date of inspection	Complied
	Regulatory status of diluent (WFI) in Pakistan is required with details of manufacturer and Registration No.	We are not providing any diluent with suspension as mentioned in label of pack that use boil water for reconstitution	Clarified
	Provide details of container closure system (Glass bottle Type) and submit suitability testing as per pharmacopeia.	CoA of glass bottle has been provided	Glass type, specification/ quality tests (as per pharmacopeia) has not been provided.
	Provide details of comparator product (Batch No and Exp date) under pharmaceutical equivalence study.	Duricef 250mg/5ml powder for oral suspension by GSK Batch No: TC3T Exp date: 08-24	
	Provide details regarding volume of diluent to be used for reconstitution to achieve label claim 125mg/5ml along with weight/ml calculation with reference to innovator's product	60ml of diluent to be used for reconstitution to achieve label claim 125mg/5ml and 250mg/5ml	Pack size/ total volume (per pack) to be clarified. Since comparator product's pack size is 90ml.
	Provide commercial invoice of API (by Medisave pharmaceuticals) and clearance by I&E DRAP	Commercial invoice of Cefadroxil (micronized) batch No 00169 cleared by I&E DRAP dated 29.01.2020 in the name of M/s Medisave Pharmaceuticals.	Complied
	In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products en.pdf)	In use stability data (reconstituted form) provided for 14 days.	Stability Data of trial batch is provided performed at initial time point.

Decision: Approved. Approved. Registration letter will be issued upon submission of following:

i. In-use stability data (reconstituted form) at the recent most time point of stability studies.

ii. Proposed fill volume after reconstitution.

iii. Type of glass container

	• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
279.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate dated 20.04.2023 based on inspection dated 03.04.2023 valid for 2 years.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 07.06.2022 specifying Capsule (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No: 13385 dated 30.05.2023
	Details of fee submitted	PKR 30,000/- Dated 17-05-2023
	The proposed proprietary name / brand name	Cefaxil 500mg capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefadroxil monohydrate eq. to Cefadroxil …….500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin (Antibacterial)
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x10’s, 2x10’s, 2x6’s As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Duricef 500mg capsule M/s GSK (Reg No 008013)
	Name and address of API manufacturer.	ACS Dobfar S.P.A Via Marzabotto, 1,7/9-20871 Vimercate (MB)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its

		validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Duricef 500mg Capsule by GSK, Quality parameters such as identification, Dissolution and Assay were compared. CDP has been performed against the same brand that is Duricef 500mg Capsule by GSK in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range
	Analytical method validation study of product	Firm has submitted analytical method verification study reports for drug substance and drug product.

STABILITY STUDY DATA			
Manufacturer of API	ACS Dobfar S.P.A Via Marzabotto, 1,7/9-20871 Vimercate (MB		
API Lot No.	00199		
Description of Pack (Container closure system)	Alu-Alu blister (2x6's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	TJD001	TJD002	TJD003
Batch Size	1400 Cap	1400 Cap	1400 Cap
Manufacturing Date	07-2022	07-2022	07-2022

Date of Initiation	21-07-2022	22-07-2022	23-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No IT-API/51/H/2019 based on inspection dated 26/10/2018 issued by AIFA valid till 42 months from the date of inspection
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided loan letter dated 02.07.2022 from M/s Medisave Pharmaceuticals, regarding borrowing API (cefadroxil monohydrate)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1	Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Firm has provided copy of GMP certificate No IT-API/51/H/2023 based on inspection dated 26/05/2023 issued by AIFA valid till 42 months from the date of inspection	Complied
2	Provide details of comparator product (Batch No and Exp date) under pharmaceutical equivalence study.	Duricef 500mg Capsule by GSK Batch No: 649X Exp date: 10/2024	
3	Provide Drug-excipient compatibility study with Sodium Lauryl Sulphate (being qualitatively different from innovator's formulation).	Provided	API Cefadroxil Monohydrate (compacted) found compatible with SLS.
4	Provide commercial invoice of API (by Medisave pharmaceuticals) and clearance by I&E DRAP	Commercial invoice of Cefadroxil (compacted) batch No 00199 cleared by I&E DRAP dated 29.01.2020 in the name of M/s Medisave Pharmaceuticals.	Complied

Decision: Approved.

	• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
280.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate dated 20.04.2023 based on inspection dated 03.04.2023 valid for 2 years.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 07.06.2022 specifying Dry Powder injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No: 21301 dated 29.08.2023
	Details of fee submitted	PKR 30,000/- Dated 03-08-2023
	The proposed proprietary name / brand name	**Ceftazidime Powder for Injection 250mg IM/IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftazidime (as Ceftazidime Pentahydrate) …….……250mg
	Pharmacotherapeutic Group of (API)	Cephalosporin (Antibacterial)
	Pharmaceutical form of applied drug	Powder for injection
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftazidime 250mg powder for solution of injection IM/IV MHRA approved
	For generic drugs (me-too status)	Fortazim 250mg injection IM/IV Reg No 015819 M/s GSK Pakistan Ltd
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical Co., Ltd Address No 849 Dongjia Town, Licheng District, Jinan, Shandong Province , China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties,

		solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Fortum Injection 250mg IM/IV by GSK, Quality parameters such as appearance, LOD, Ph, average content weight, assay, limit of pyridine, sodium carbonate were compared.
	Analytical method validation study of product	Firm has submitted analytical method verification study reports for drug substance and drug product.

STABILITY STUDY DATA			
Manufacturer of API	Qilu Antibiotics Pharmaceutical Co., Ltd Address No 849 Dongjia Town, Licheng District, Jinan, Shandong Province , China		
API Lot No.	2551LJ81JD		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	TJN001	TJN002	TJN003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	28-12-2022	29-12-2022	30-12-2022

No. of Batches	03	
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No SD20180660 dated 09/02/2018 issued by China Food and Drug Administration valid till 08th Februar 2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided loan letter from M/s Medisave Pharmaceuticals, regarding borrowing API. Firm has provided commercial invoice no CIHMBC/04/12/311 dated 01.11.2022 regarding purchase of 50Kg Ceftazidime pentahydrate with sodium carbonate USP Batch No 2551LJ81JD. Clearance certificate dated 19-Dec-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr. #	Observations	Reply	Remarks
1	Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Firm has provided copy of DML No 20160006 issued by Food and Drug Administration of Guangdong Province dated 04.11.2020 valid till 03.11.2025	Complied
2	Regulatory status of diluent (WFI) in Pakistan is required with details of manufacturer and Registration No.	WFI 5ml by M/s Wimits pharmaceuticals Reg No 096744 WFI 3ml, 5ml and 10ml by M/s Bosch pharmaceuticals Reg No 073420	Provided
3	The potency of ceftazidime base mentioned in batch formula as 77%. Whereas % of ceftazidime mentioned in CoA by DS manufacturer as 99.5% (on the dried and sodium carbonate--free basis). Justify it	Assay of ceftazidime form mentioned in CoA by DS manufacturer as 99.5% while ceftazidime form is ceftazidime pentahydrate with sodium carbonate Ceftazidime base = 99.5%-10.1%-12.3% = 77%	Justified

		Water content=12.3% Sodium carbonate=10.1%	
4	Justify quantity of Ceftazidime Pentahydrate (with sodium carbonate) mentioned in Master formula i.e 324.25 mg/vial	Ceftazidime base assay = 77% (on As is basis) Ceftazidime for injection=100/77x250 = 324.67mg	Justified
5	Provide details of container closure system (Glass vial Type) and submit suitability testing as per pharmacopeia.	Glass vial type is mentioned as "USP Type II" Results of suitability test (as per USP) i.e Glass grain test and surface glass test have been provided	complied
6	Provide details of comparator product (Batch No and Exp date) under pharmaceutical equivalence study.	Fortazim 0.25g injection By Bosch pharmaceutical Batch No A230901 Exp 03-26	provided
7	In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products en.pdf)	In use stability data (reconstituted form) is provided for batch No TJN001 up to 24 hours. All pharmacopoeial parameters were tested and found within limit	provided

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

281.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate dated 20.04.2023 based on inspection dated 03.04.2023 valid for 2 years.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 07.06.2022 specifying Dry Powder injection (Cephalosporin) section.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No: 20814 dated 23.08.2023
	Details of fee submitted	PKR 30,000/- Dated 03-08-2023
	The proposed proprietary name / brand name	**Ceftazidime Powder for Injection 1g IM/IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftazidime (as Ceftazidime Pentahydrate) …… 1g
	Pharmacotherapeutic Group of (API)	Cephalosporin (Antibacterial)
	Pharmaceutical form of applied drug	Powder for injection
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftazidime 1g powder for injection IM/IV MHRA approved
	For generic drugs (me-too status)	Fortazim 1g injection IM/IV Reg No 025114
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical Co., Ltd Address No 849 Dongjia Town, Licheng District, Jinan, Shandong Province , China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(50001CJ81J-C,50003CJ81J-C 50005CJ81J-C)

	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Fortum Injection 1g IM/IV by GSK, Quality parameters such as appearance, LOD, Ph, average content weight, assay, limit of pyridine, sodium carbonate were compared.
	Analytical method validation study of product	Firm has submitted analytical method verification study reports for drug substance and drug product.

STABILITY STUDY DATA			
Manufacturer of API	Qilu Antibiotics Pharmaceutical Co., Ltd Address No 849 Dongjia Town, Licheng District, Jinan, Shandong Province , China		
API Lot No.	2551LJ81JD		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	TJP001	TJP002	TJP003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	05-01-2023	06-01-2023	07-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No SD20180660 dated 09/02/2018 issued by China Food and Drug Administration valid till 08th Februar 2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided loan letter from M/s Medisave Pharmaceuticals, regarding borrowing API. Firm has provided commercial invoice no CIHMBC/04/12/311 dated 01.11.2022 regarding purchase of 50Kg Ceftazidime pentahydrate with sodium carbonate USP Batch No 2551LJ81JD. Clearance certificate dated 19-Dec-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

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

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1	Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Firm has provided copy of DML No 20160006 issued by Food and Drug Administration of Guangdong Province dated 04.11.2020 valid till 03.11.2025	Complied
2	Regulatory status of diluent (WFI) in Pakistan is required with details of manufacturer and Registration No.	WFI 5ml by M/s Wimits pharmaceuticals Reg No 096744 WFI 3ml, 5ml and 10ml by M/s Bosch pharmaceuticals Reg No 073420	Provided
3	The potency of ceftazidime base mentioned in batch formula as 77%. Whereas % of ceftazidime mentioned in CoA by DS manufacturer as 99.5% (on the dried and sodium carbonate--free basis). Justify it	Assay of ceftazidime form mentioned in CoA by DS manufacturer as 99.5% while ceftazidime form is ceftazidime pentahydrate with sodium carbonate Ceftazidime base = 99.5%-10.1%-12.3% = 77% Water content=12.3% Sodium carbonate=10.1%	Justified
4	Justify quantity of Ceftazidime Pentahydrate (with sodium carbonate) mentioned in Master formula i.e 1297.02 mg/vial	Ceftazidime base assay = 77% (on As is basis) Ceftazidime for injection=100/77x1000 = 1298mg	Justified
5	Provide details of container closure system (Glass vial Type) and submit suitability testing as per pharmacopeia.	Glass vial type is mentioned as "USP Type II" Results of suitability test (as per USP) i.e Glass grain test and surface glass test have been provided	Complied
	Provide details of comparator product (Batch No and Exp date) under pharmaceutical equivalence study.	Fortazim 1g injection By Bosch pharmaceutical Batch No A230624 Exp 11-25	Provided
6	In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-	In use stability data (reconstituted form) is provided for batch No TJP001 up to 24 hours. All pharmacopoeial parameters were tested and found within limit	Provided

	guidance-use-stability-testing-human-medicinal-products en.pdf)		

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

282.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate dated 20.04.2023 based on inspection dated 03.04.2023 valid for 2 years.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 07.06.2022 specifying Dry Powder injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No: 20813 dated 23.08.2023
	Details of fee submitted	PKR 30,000/- Dated 03-08-2023
	The proposed proprietary name / brand name	**Ceftazidime Powder for Injection 500mg IM/IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftazidime (as Ceftazidime Pentahydrate) …….……500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin (Antibacterial)
	Pharmaceutical form of applied drug	Powder for injection
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftazidime 500mg powder for solution of injection IM/IV MHRA approved
	For generic drugs (me-too status)	Fortazim 500mg injection IM/IV Reg No 025113
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical Co., Ltd Address No 849 Dongjia Town, Licheng District, Jinan, Shandong Province , China

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(50001CJ81J-C,50003CJ81J-C 50005CJ81J-C)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Fortum Injection 500mg IM/IV by GSK, Quality parameters such as appearance, LOD, Ph, average content weight, assay, limit of pyridine, sodium carbonate were compared.
	Analytical method validation study of product	Firm has submitted analytical method verification study reports for drug substance and drug product.

STABILITY STUDY DATA			
Manufacturer of API	Qilu Antibiotics Pharmaceutical Co., Ltd Address No 849 Dongjia Town, Licheng District, Jinan, Shandong Province , China		
API Lot No.	2551LJ81JD		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	TJO001	TJO002	TJO003

Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	02-01-2023	03-01-2023	04-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No SD20180660 dated 09/02/2018 issued by China Food and Drug Administration valid till 08th Februar 2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided loan letter from M/s Medisave Pharmaceuticals, regarding borrowing API. Firm has provided commercial invoice no CIHMBC/04/12/311 dated 01.11.2022 regarding purchase of 50Kg Ceftazidime pentahydrate with sodium carbonate USP Batch No 2551LJ81JD. Clearance certificate dated 19-Dec-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr. #	Observations	Reply	Remarks
1	Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Firm has provided copy of DML No 20160006 issued by Food and Drug Administration of Guangdong Province dated 04.11.2020 valid till 03.11.2025	Complied
2	Regulatory status of diluent (WFI) in Pakistan is required with details of manufacturer and Registration No.	WFI 5ml by M/s Wimits pharmaceuticals Reg No 096744 WFI 3ml, 5ml and 10ml by M/s Bosch pharmaceuticals Reg No 073420	Provided
3	The potency of ceftazidime base mentioned in batch formula as 77%. Whereas % of ceftazidime mentioned in CoA by DS manufacturer as 99.5% (on the dried and sodium carbonate--free basis). Justify it	Assay of ceftazidime form mentioned in CoA by DS manufacturer as 99.5% while ceftazidime form is ceftazidime pentahydrate with sodium carbonate Ceftazidime base = 99.5%-10.1%-12.3%	Justified

		= 77% Water content=12.3% Sodium carbonate=10.1%	
4	Justify quantity of Ceftazidime Pentahydrate (with sodium carbonate) mentioned in Master formula i.e 681.51mg/vial	Ceftazidime base assay = 77% (on As is basis) Ceftazidime for injection=100/77x500 = 649.35mg 681.51mg/vial was mentioned due to typographic error.	Justified
5	Provide details of container closure system (Glass vial Type) and submit suitability testing as per pharmacopeia.	Glass vial type is mentioned as "USP Type II" Results of suitability test (as per USP) i.e Glass grain test and surface glass test have been provided	Complied
6	Provide details of comparator product (Batch No and Exp date) under pharmaceutical equivalence study.	Fortazim 500mg injection By Bosch pharmaceutical Batch No A230929 Exp 04-26	Provided
7	In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products en.pdf)	In use stability data (reconstituted form) is provided for batch No TJO001 up to 24 hours. All pharmacopoeial parameters were tested and found within limit	Provided

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

283.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare Pvt. Ltd. Address : Plot #35-A, Small Industrial Estate, Taxila**
	Name, address of Manufacturing site.	M/s Horizon Healthcare Pvt. Ltd. Address : Plot #35-A, Small Industrial Estate, Taxila
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate dated 17.8.2022 based on inspection dated 16.08.2022 valid for 2 years till 15.08.2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of additional section dated 25-10-2023 specifying Dry Powder for Inhalation section.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID J58-AYE-Z8L2 Application No: 660 Submitted on e-app dated 10th January 2024
	Details of fee submitted	PKR 30,000/- Dated 14-11-2023
	The proposed proprietary name / brand name	**Glycopep 50mcg DPI Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Glycopyrronium (as Bromide) …….50mcg Each delivered dose – (the dose that leaves the mouth piece of the inhaler) contains Glycopyrronium (as Bromide)……..44mcg
	Pharmacotherapeutic Group of (API)	Long acting Bronchodilator. Anti-Muscarinic agent
	Pharmaceutical form of applied drug	Inhalation powder, hard capsule
	Reference to Finished product specifications	As per Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	EMA approved Seebri Breezhaler 50mcg, Dry powder Inhalation Capsule. M/s Novartis Pharmaceuticals UK Ltd
	For generic drugs (me-too status)	Glynvair 50mcg Rotacap Highnoon Laboratory Reg No 115683
	Name and address of API manufacturer.	MELODY HEALTHCARE PVT. LTD. UNIT-1: PLOT NO. J-73, M.I.D.C Tarapur, Boisar, Dist., Palghar, 401506. Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 18 months

		Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(GLY20003, GLY20004, GLY20005)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Glynvair 50mcg Rotacap by Highnoon Quality parameters such as appearance, uniformity of capsule weight, uniformity of content weight, water content, assay, microbial limit, uniformity of delivered dose and aerodynamic assessment of particle size were compared.
	Analytical method validation study of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	MELODY HEALTHCARE PVT. LTD. UNIT-1: PLOT NO. J-73, M.I.D.C Tarapur, Boisar, Dist., Palghar, 401506. Maharashtra, India		
API Lot No.	GLY/23002		
Description of Pack (Container closure system)	PA/Alu/PVC – Alu perforated unit-dose blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	GLC-001	GLC-002	GLC-003
Batch Size	2000 Cap	2000 Cap	2000 Cap
Manufacturing Date	07-2023	07-2023	07-2023
Date of Initiation	05-07-2023	06-07-2023	07-07-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate dated 20/03/2020 issued by Food and Drug Administration Bandra Kurla Complex valid till 19th March 2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided clearance certificate dated 22.06.2023 wherein 0.02 Kg Glycopyrrolate (USP) was purchased (Batch No GLY/23002)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

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

Remarks of Assessor:

Inhaler device: Rotazon

Sr.#	Sections	Observations	Reply	Remarks
1	3.2.P.2	Description of Packaging (Container closure system) is to be provided, also provide details of metered dose inhalation device i.e Rotazon (name, model, manufacturer, shelf life) provided in pack.	Firm has provided details of inhalation device as follows: Name: Rotazon inhaler device Model: DL-D02 Manufacturer: Taian Dalu Medical Instrument Co., Ltd West part of yitianmen street, Hi-tech zone, Taian, Shandong, China Shelf life: 3 years	Complied
2	3.2.P.2.2.1	Provide details of comparator product against which pharmaceutical equivalence study was performed. It should reveal, brand name, manufacturer, batch no. and expiry date	Glynvair 50mcg Rotacap by Highnoon Batch No: 232146 Exp date: 04/2025	Complied
3	3.2.P.8	Provide Stability data including summary data sheet, chromatograms, CoA and raw data sheets (both accelerated and real time) for 6th month period and onward.	Provided	Complied

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

284.	Name, address of Applicant / Marketing Authorization Holder	M/s Obsons Pharmaceuticals 209-S Quaid e azam Industrial estate, Kot Lakhpat Lahore.
	Name, address of Manufacturing site.	M/s Obsons Pharmaceuticals 209-S Quaid e azam Industrial estate, Kot Lakhpat Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has provided GMP certificate based on inspection dated 22.02.2022

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 14-09-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23578 (R&I) DRAP, dated 19/08/2022
	Details of fee submitted	PKR 30,000/- Dated 09-06-2022
	The proposed proprietary name / brand name	**Welflox Tablet 250mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin hemihydrate eq to Levofloxacin……..….250mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolone
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 10's, 2 x 10's, 3 x 10's,
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Leflox 250mg tablet by M/s Getz pharma, Pakistan.
	Name and address of API manufacturer.	Zhejiang East-Asia Pharmaceutical Co Ltd, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(DC-004-1512001, DC-04-1512001, DC-004-1512003)

	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Leflox 250mg tablet by M/s Getz pharma, Pakistan. (Batch No F03008) (Exp date 02/2025) Quality parameters such as identification, dissolution, DT, content uniformity, average weight. Moisture content and assay etc were compared against Ob-Flox 250mg Tablet (Batch No 470) CDP has been performed against the same brand that is Leflox 250mg tablet by M/s Getz pharma, Pakistan (Batch No F03008) in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Zhejiang East-Asia Pharmaceutical Co Ltd, China		
API Lot No.	DC-004-1806013		
Description of Pack (Container closure system)	Alu-Alu Blister (1x10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6,9,12,18 and 24 (Months)		
Batch No.	025	089	091
Batch Size	100,000 tab	100,000 tab	100,000 tab
Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	18-10-2019	24-10-2019	26-10-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No ZJ20160079 valid till 15th August 2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# LEV181029-L dated 29th October 2018, with received quantity i.e. 300Kg) batch no. DC-004-1806013for the purchase of Levofloxacin

		hemihydrate from Zhejiang East-Asia Pharmaceutical Co Ltd. China with attestation of DRAP dated 01/11/2018
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided

Remarks of Assessor:

Sr.#	Observation	Reply	Remarks
1	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided	Firm has provided copy of GMP certificate dated 29.07.2021 valid till 28th July 2026 issued by Sanmen Market Supervision Administration China	Complied
2	2.3.S.5 COA of primary / secondary reference standard including source and lot number to be provided	Not provided	Not complied
3	3.2.S.4 Analytical Method Verification studies of Drug Substance performed by the Drug Product manufacturer to be provided including results of accuracy, precision and specificity etc	Provided	Complied
4	3.2.P.2 Provide Drug excipients compatibility study report for Primogel and PVP-K30 being qualitatively different from innovator product	Provided	Complied
5	3.2.P.5 Under Analytical Method Verification studies of Drug Product results of accuracy and specificity parameter (against sample, standard, placebo and blank) performed by the Drug Product manufacturer to be provided	Provided	Complied
6	3.2.P.8 Under stability data wavelength at which assay of drug was detected has not been clarified in chromatograms.	Chromatogram has been submitted wherein wavelength is mentioned as 360nm.	Wavelength at which assay of drug was detected is 360nm (as per USP)

Decision: Registration Board approved the application. Before issuance of registration letter firm will Provide COA of primary / secondary reference standard including source and lot number.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Registration applications of New License (Human):

285.	Name, address of Applicant / Marketing Authorization Holder	**M/s Albarkat Pharmaceuticals Industries, Plot No, B-66A, S.I.T.E Noori abad, jamshoro**
	Name, address of Manufacturing site.	M/s Albarkat Pharmaceuticals Industries, Plot No, B-66A, S.I.T.E Noori abad, jamshoro
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection for grant of DML was conducted on 12.04.2023
	Evidence of approval of manufacturing facility	Liquid Ampoule (General), approval and granted by DRAP (Central Licensing Board) vide letter No. F. 2-7/2017-Lic, dated: 18-10-2023.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID QX6-QNW-BSE7 dated 01-03-2024
	Details of fee submitted	Rs.30,000/- dated 22-01-2024
	The proposed proprietary name / brand name	**Alfenac 75mg/3ml solution for injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Diclofenac sodium ……75mg /3ml
	Pharmacotherapeutic Group of (API)	Anti-inflammatory and Ant rheumatic drug , non-steroids
	Pharmaceutical form of applied drug	Solution for injection
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	3mlx10’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Econac injection 75mg/3ml MHRA approved
	For generic drugs (me-too status)	Voren injection 75mg/3ml (Reg No 007737) By Asian continental
	Name and address of API manufacturer.	Aarti Drugs Limited, Plot No 109-D, Road No 29-Sion (East) Mumbai. India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	The firm submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of both drug substances at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months DFS/301002, DFS/305060, DFS/309136
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not provided
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	Aarti Drugs Limited, Plot No 109-D, Road No 29-Sion (East) Mumbai. India		
API Lot No.	DFS/11040129		
Description of Pack (Container closure system)	Amber glass ampoule 3ml		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DF-TB-001	DF-TB-002	DF-TB-003
Batch Size	2500 ampoules	2500 ampoules	2500 ampoules
Manufacturing Date	05-2023	05-2023	05-2023
Date of initiation	18/05/2023	18/05/2023	18/05/2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Retention of License (w.e.f 01/01/2022 up to 31.12.2026) is provided dated 05.01.2022

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial invoice No Exp/265/21-22 dated 22.04.2021 is provided wherein 1000kg diclofenac sodium (Batch No DFS/11040129 in the name of ISIS pharmaceuticals and chemical works. Approved by I&E DRAP dated 02.07.2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Provided
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

S.No	Observations	Reply	Remarks
1	**2.3.P.6** COA of primary / secondary reference standard including source and lot number to be provided	*CoA of working standard (diclofenac sodium) is provided which has been standardized against USP standard.*	Drug substance specification/ analytical method adopted was as per BP. However, USP reference standard was used.
2	**3.2.S.4** Analytical method verification study of Drug Substance to be performed by Drug Product manufacturer	Provided under module 3 section 3.2.S.4.3	Analytical method verification study of Drug substance performed by Drug substance manufacturer instead of drug product manufacturer.
3	**3.2.P.2** Provide details of container closure system (Glass ampoule) such as glass type and suitability testing/Quality testing (as per relevant pharmacopeia) to be submitted	USP type I glass ampoule	Method of quality testing (as per USP) has been provided instead of performance report/results.
4	**3.2.P.2.2.1** Provide Pharmaceutical equivalence study and details of comparator/Reference product such as Exp. Date, Batch no. etc against which Pharmaceutical equivalence study was performed.	Pharmaceutical equivalence study performed against Voren injection by Asian continental (Batch No S2232, Exp date 10/2022)	

		Parameters compared were appearance, Ph and assay.	
5	**3.2.P.5:** Finished product specification mentioned on Form5F as USP while applied formulation is not found in any official monograph. Clarify applied finished product specification.	There is a typographic error in Form5F, the specification of mentioned product is **Albarakat specification**.	Data to be submitted as per 'Guidance document regarding application of Drug Product specification' vide No.9-2/2022-PEC dated 18.12.2023 Moreover fee (Rs 7500/-) is required for correction of finished product specification mentioned in Form5F.
6	**3.2.P.8** Provide loan agreement for borrowing API from M/s ISIS pharmaceuticals and chemical works, Karachi	Loan agreement for borrowing API (250g) from M/s ISIS pharmaceuticals and chemical works, Karachi is provided dated 02.05.2023	

Decision: Deferred for following shortcomings:

a) **Drug substance specification/ analytical method adopted was as per BP whereas USP reference standard was used.**
b) **Analytical method verification study of Drug Substance performed by Drug Product manufacturer is required.**
c) **Results of quality testing of USP type I glass ampoule (as per USP) to be submitted.**
d) **Since firm adopted finished product specification as manufacturer's specification hence needs to fulfil the crieteria as laid down in 'Guidance document regarding application of Drug Product specification' vide No.9-2/2022-PEC dated 18.12.2023 and submit data accordingly.**

Agenda of Evaluator PEC-XXI

Agenda Item No. 01:

Routine Applications of Human Drugs (Locally Manufactured) applied on Form - 5F.

286.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 106/2020-DRAP(AD-1904818-970) dated 06-07-2020 valid for two years from the date of inspection (09-06-2020) has been submitted.
	Evidence of approval of manufacturing facility	Copy of letter for Renewal of DML vide No. F. 1-20/2006-Lic (Vol-II) dated 30th June, 2020 contains section approval for: - • **Tablet Section (General).** • Capsule Section (General). • Dry Powder Sachet Section (General). • Oral Liquid Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17529 dated 15 JUN 2022
	Details of fee submitted	PKR 30,000/- Dated 19-05-2022 (Challan / Receipt # 71707186772)
	The proposed proprietary name / brand name	**ROXISTAT 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Rosuvastation (as calcium) … 5mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	C10AA07, HMG CoA reductase inhibitors
	Pharmaceutical form of applied drug	Round, biconvex, yellow colored film coated tablet, with both plain sides.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CROSUVA 5mg Tablets, TGA Approved.
	For generic drugs (me-too status)	RUVASTAT 5mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd.
	Name and address of API manufacturer.	M/s Zhejiang Menovo Pharmaceutical Co. Ltd. No. 8 Jing 13 Road, Hangzhou Gulf, Shangyu Economic and Technological Development Zone, 312369 China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities,

		physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 Months. The real time stability data is conducted at 5°C ± 3°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against RUVASTAT 5mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against RUVASTAT 5mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Menovo Pharmaceutical Co. Ltd. China.		
API Lot No.	ROI-7-09210501		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	09-2021	10-2021	10-2021
Date of Initiation	09-2021	10-2021	10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate issued by Zhejiang Medical Products Services Centre for Information Publicity and Development, **valid till Aug 24, 2023.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Clearance (vide No. 11450/2021 DRAP dated 02-08-2021) by AD I&E DRAP, Lahore has been submitted for 1.5KGs Rosuvastatin Calcium Batch No. ROI-7-09210501 vide Invoice No. 21ZJ027 dated 2021-6-30.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail reports on product testing has been submitted. **Compliance Record of HPLC software 21CFR has not been submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

	Deficiencies / Shortcomings	Response of the firm
i.	Please confirm the name of Firm as it is mentioned as "M/s Axis Pharmaceuticals (Pvt.) Ltd." on enclosed copy of DML and on Renewal of your DML whereas the same is mentioned as "M/s Axis Pharmaceuticals" throughout your application. Please provide supporting documents for the same.	The firm has submitted correced copy of DML as "M/s Axis Pharmaceuticals".
ii.	2.3.P.3.2 The application has been claimed to be submitted for 'film coated tablet', whereas no ingredient for preparation of film coating has been mentioned in this section. Please clarify.	The firm has submitted revised Section 2.3.P.3.2 mentioning information of film coating.
iii.	2.3.P.5 Please specify the USP Dissolution Test (1 or 2).	The firm has specified USP Test – I for performing Dissolution Test.
iv.	2.3.P.5 USP recommends "Column: 4.6-mm × 5-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Dissolution Analysis. Please justify.	The firm has claimed that the analytical method was adjusted as per actual practice.
v.	2.3.P.5 USP recommends "Column: 3.2-mm × 25-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Assay / Content Uniformity. Please Justify	The firm has claimed that the analytical method was adjusted as per actual practice.
vi.	2.3.P.5 Moreover, the Flow Rate and Injection volume are also different from that recommended in USP Monograph for Rosuvastatin Tablets. Please justify.	The firm has claimed that the analytical method was adjusted as per actual practice.

vii.	2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.	The firm has committed that USP Reference Standard will be used for standardization upon commercialization of drug product.
viii.	3.2.S.7.1 The real time stability data of drug substance is conducted at 25°C± 2°C/60% RH ± 5% RH, however for locally manufactured products the stability studies of the Drug substance shall be submitted as per Zone-IV(a) conditions.	The firm has submitted that the recommended storage conditions for Rosuvastatin Calcium is 2°C - 8°C as per Drug Substance Manufacturer, hence the real time stability data of drug substance is conducted at 25°C± 2°C/60% RH ± 5% RH.
ix.	Furthermore, in case of use of ingredients whose stability testing has not been done as per Zone-IV(a), the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product along with degradation studies in the finished pharmaceutical product. No such data on degradation studies has been submitted. Please clarify.	Same as above.
x.	3.2.P.2.1.1 Pharmaceutical equivalence / CDP has been performed against 'RUVASTAT 5mg Tablets' instead of the Reference / Innovator's Product. Please justify.	The firm has stated that Comparator product was used as it was readily available.
xi.	Please provide Compliance Record of HPLC Software 21CFR.	Certificate of 21CFR Compliance of HPLC Software has not been submitted.
xii.	The submitted Audit trail reports on product testing mentions "Year 2017" on multiple instances, whereas the product was developed in the year 2021. Please justify.	The firm has stated that *"Roxistat Tablets were developed in 2021, however, the testing method created in HPLC software are saved in a default folder titled "Year 2017", created in year 2017 which is linked to the backup folder on server. Therefore, Year 2017 apears on Audit Trail Reports indicating project location".*
xiii.	Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed copy of GMP Certificate is not from the concerned regulatory authority of country of origin and was valid till Aug 24, 2023.	Copy of GMP Certificate No. ZJ20190121 dated 10/28/2019 issued by CFDA has been submitted.
xiv.	Please provide GMP status of the FPP manufacturer (not older than 03 years).	Copy of GMP Certificate Ref. No. 100/2022-DRAP(AD-51001963034) dated 20-06-2022 valid for two years from the date of inspection (13-06-2022) has been submitted. Cinaxipid Tablet 1mg, Axistart-K Tablets, Trubax Tablets etc.

xv.	Please provide Reference of previous approval of applications with stability study data of the firm (if any)	

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction / Typographical Mistake.**
- **Justification / clarification for points below are needed;**
  - **2.3.P.5 USP recommends "Column: 4.6-mm × 5-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Dissolution Analysis.**
  - **2.3.P.5 USP recommends "Column: 3.2-mm × 25-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Assay / Content Uniformity.**
  - **2.3.P.5 Moreover, the Flow Rate and Injection volume are also different from that recommended in USP Monograph for Rosuvastatin Tablets.**
  - **2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.**

287.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 106/2020-DRAP(AD-1904818-970) dated 06-07-2020 valid for two years from the date of inspection (09-06-2020) has been submitted.
	Evidence of approval of manufacturing facility	Copy of letter for Renewal of DML vide No. F. 1-20/2006-Lic (Vol-II) dated 30th June, 2020 contains section approval for: - • **Tablet Section (General).** • Capsule Section (General). • Dry Powder Sachet Section (General). • Oral Liquid Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17530 dated 15 JUN 2022
	Details of fee submitted	PKR 30,000/- Dated 19-05-2022 (Challan / Receipt # 2569143907)
	The proposed proprietary name / brand name	**ROXISTAT 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Rosuvastation (as calcium) … 10mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	C10AA07, HMG CoA reductase inhibitors
	Pharmaceutical form of applied drug	Round, biconvex, brown colored film coated tablet, with both plain sides.

	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CROSUVA 10mg Tablets, TGA Approved.
	For generic drugs (me-too status)	RUVASTAT 10mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd.
	Name and address of API manufacturer.	M/s Zhejiang Menovo Pharmaceutical Co. Ltd. No. 8 Jing 13 Road, Hangzhou Gulf, Shangyu Economic and Technological Development Zone, 312369 China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 Months. The real time stability data is conducted at 5°C ± 3°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against RUVASTAT 10mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against RUVASTAT 10mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Zhejiang Menovo Pharmaceutical Co. Ltd. China.
API Lot No.	ROI-7-09210501

Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	09-2021	10-2021	10-2021
Date of Initiation	09-2021	10-2021	10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate issued by Zhejiang Medical Products Services Centre for Information Publicity and Development, **valid till Aug 24, 2023.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Clearance (vide No. 11450/2021 DRAP dated 02-08-2021) by AD I&E DRAP, Lahore has been submitted for 1.5KGs Rosuvastatin Calcium Batch No. ROI-7-09210501 vide Invoice No. 21ZJ027 dated 2021-6-30.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail reports on product testing has been submitted. **Compliance Record of HPLC software 21CFR has not been submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

Deficiencies / Shortcomings	Response of the firm
i. Please confirm the name of Firm as it is mentioned as "M/s Axis Pharmaceuticals (Pvt.) Ltd." on enclosed copy of DML and on Renewal of your DML whereas the same is mentioned as "M/s Axis Pharmaceuticals" throughout your application. Please provide supporting documents for the same.	The firm has submitted correced copy of DML as "M/s Axis Pharmaceuticals".
ii. 2.3.P.3.2 The application has been claimed to be submitted for 'film coated tablet',	The firm has submitted revised Section 2.3.P.3.2 mentioning information of film coating.

	whereas no ingredient for preparation of film coating has been mentioned in this section. Please clarify.	
iii.	2.3.P.5 Please specify the USP Dissolution Test (1 or 2).	The firm has specified USP Test – I for performing Dissolution Test.
iv.	2.3.P.5 USP recommends "Column: 4.6-mm × 5-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Dissolution Analysis. Please justify.	The firm has claimed that the analytical method was adjusted as per actual practice.
v.	2.3.P.5 USP recommends "Column: 3.2-mm × 25-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Assay / Content Uniformity. Please Justify	The firm has claimed that the analytical method was adjusted as per actual practice.
vi.	2.3.P.5 Moreover, the Flow Rate and Injection volume are also different from that recommended in USP Monograph for Rosuvastatin Tablets. Please justify.	The firm has claimed that the analytical method was adjusted as per actual practice.
vii.	2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.	The firm has committed that USP Reference Standard will be used for standardization upon commercialization of drug product.
viii.	3.2.S.7.1 The real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ± 5% RH, however for locally manufactured products the stability studies of the Drug substance shall be submitted as per Zone-IV(a) conditions.	The firm has submitted that the recommended storage conditions for Rosuvastatin Calcium is 2°C - 8°C as per Drug Substance Manufacturer, hence the real time stability data of drug substance is conducted at 25°C± 2°C/60% RH ± 5% RH.
ix.	Furthermore, in case of use of ingredients whose stability testing has not been done as per Zone-IV(a), the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product along with degradation studies in the finished pharmaceutical product. No such data on degradation studies has been submitted. Please clarify.	Same as above.
x.	3.2.P.2.1.1 Pharmaceutical equivalence / CDP has been performed against 'RUVASTAT 10mg Tablets' instead of the Reference / Innovator's Product. Please justify.	The firm has stated that Comparator product was used as it was readily available.
xi.	Please provide Compliance Record of HPLC Software 21CFR.	Certificate of 21CFR Compliance of HPLC Software has not been submitted.

xii.	The submitted Audit trail reports on product testing mentions "Year 2017" on multiple instances, whereas the product was developed in the year 2021. Please justify.	The firm has stated that *"Roxistat Tablets were developed in 2021, however, the testing method created in HPLC software are saved in a default folder titled "Year 2017", created in year 2017 which is linked to the backup folder on server. Therefore, Year 2017 apears on Audit Trail Reports indicating project location".*
xiii.	Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed copy of GMP Certificate is not from the concerned regulatory authority of country of origin and was valid till Aug 24, 2023.	Copy of GMP Certificate No. ZJ20190121 dated 10/28/2019 issued by CFDA has been submitted.
xiv.	Please provide GMP status of the FPP manufacturer (not older than 03 years).	Copy of GMP Certificate Ref. No. 100/2022-DRAP(AD-51001963034) dated 20-06-2022 valid for two years from the date of inspection (13-06-2022) has been submitted.
xv.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	Cinaxipid Tablet 1mg, Axistart-K Tablets, Trubax Tablets etc.

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction / Typographical Mistake.**
- **Justification / clarification for points mentioned below;**
  - **2.3.P.5 USP recommends "Column: 4.6-mm × 5-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Dissolution Analysis.**
  - **2.3.P.5 USP recommends "Column: 3.2-mm × 25-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Assay / Content Uniformity.**
  - **2.3.P.5 Moreover, the Flow Rate and Injection volume are also different from that recommended in USP Monograph for Rosuvastatin Tablets.**
  - **2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.**

288.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 106/2020-DRAP(AD-1904818-970) dated 06-07-2020 valid for two years from the date of inspection (09-06-2020) has been submitted.
	Evidence of approval of manufacturing facility	Copy of letter for Renewal of DML vide No. F. 1-20/2006-Lic (Vol-II) dated 30th June, 2020 contains section approval for: - • **Tablet Section (General).** • Capsule Section (General). • Dry Powder Sachet Section (General). • Oral Liquid Section (General).

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17531 dated 15 JUN 2022
	Details of fee submitted	PKR 30,000/- Dated 19-05-2022 (Challan / Receipt # 4090317687)
	The proposed proprietary name / brand name	**ROXISTAT 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Rosuvastation (as calcium) … 20mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	C10AA07, HMG CoA reductase inhibitors
	Pharmaceutical form of applied drug	Round, biconvex, orange colored film coated tablet, with both plain sides.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CROSUVA 20mg Tablets, TGA Approved.
	For generic drugs (me-too status)	RUVASTAT 20mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd.
	Name and address of API manufacturer.	M/s Zhejiang Menovo Pharmaceutical Co. Ltd. No. 8 Jing 13 Road, Hangzhou Gulf, Shangyu Economic and Technological Development Zone, 312369 China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 Months. The real time stability data is conducted at 5°C ± 3°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control,

		process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against ROSULIN 20mg Tablets by M/s Highnoon Laboratories Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against ROSULIN 20mg Tablets by M/s Highnoon Laboratories Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Menovo Pharmaceutical Co. Ltd. China.		
API Lot No.	ROI-7-09210501		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	09-2021	10-2021	10-2021
Date of Initiation	09-2021	10-2021	10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate issued by Zhejiang Medical Products Services Centre for Information Publicity and Development, **valid till Aug 24, 2023.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Clearance (vide No. 11450/2021 DRAP dated 02-08-2021) by AD I&E DRAP, Lahore has been submitted for 1.5KGs Rosuvastatin Calcium Batch No. ROI-7-09210501 vide Invoice No. 21ZJ027 dated 2021-6-30.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail reports on product testing has been submitted. **Compliance Record of HPLC software 21CFR has not been submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

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

	Deficiencies / Shortcomings	Response of the firm
i.	Please confirm the name of Firm as it is mentioned as "M/s Axis Pharmaceuticals (Pvt.) Ltd." on enclosed copy of DML and on Renewal of your DML whereas the same is mentioned as "M/s Axis Pharmaceuticals" throughout your application. Please provide supporting documents for the same.	The firm has submitted correced copy of DML as "M/s Axis Pharmaceuticals".
ii.	2.3.P.3.2 The application has been claimed to be submitted for 'film coated tablet', whereas no ingredient for preparation of film coating has been mentioned in this section. Please clarify.	The firm has submitted revised Section 2.3.P.3.2 mentioning information of film coating.
iii.	2.3.P.5 Please specify the USP Dissolution Test (1 or 2).	The firm has specified USP Test – I for performing Dissolution Test.
iv.	2.3.P.5 USP recommends "Column: 4.6-mm × 5-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Dissolution Analysis. Please justify.	The firm has claimed that the analytical method was adjusted as per actual practice.
v.	2.3.P.5 USP recommends "Column: 3.2-mm × 25-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Assay / Content Uniformity. Please Justify	The firm has claimed that the analytical method was adjusted as per actual practice.
vi.	2.3.P.5 Moreover, the Flow Rate and Injection volume are also different from that recommended in USP Monograph for Rosuvastatin Tablets. Please justify.	The firm has claimed that the analytical method was adjusted as per actual practice.
vii.	2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.	The firm has committed that USP Reference Standard will be used for standardization upon commercialization of drug product.
viii.	3.2.S.7.1 The real time stability data of drug substance is conducted at 25°C± 2°C/60% RH ± 5% RH, however for locally manufactured products the stability studies	The firm has submitted that the recommended storage conditions for Rosuvastatin Calcium is 2°C - 8°C as per Drug Substance Manufacturer, hence the

	of the Drug substance shall be submitted as per Zone-IV(a) conditions.	real time stability data of drug substance is conducted at 25°C± 2°C/60% RH ± 5% RH.
ix.	Furthermore, in case of use of ingredients whose stability testing has not been done as per Zone-IV(a), the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product along with degradation studies in the finished pharmaceutical product. No such data on degradation studies has been submitted. Please clarify.	Same as above.
x.	3.2.P.2.1.1 Pharmaceutical equivalence / CDP has been performed against 'ROSULIN 20mg Tablets' instead of the Reference / Innovator's Product. Please justify.	The firm has stated that Comparator product was used as it was readily available.
xi.	Please provide Compliance Record of HPLC Software 21CFR.	Certificate of 21CFR Compliance of HPLC Software has not been submitted.
xii.	Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed copy of GMP Certificate is not from the concerned regulatory authority of country of origin and was valid till Aug 24, 2023.	Copy of GMP Certificate No. ZJ20190121 dated 10/28/2019 issued by CFDA has been submitted.
xiii.	Please provide GMP status of the FPP manufacturer (not older than 03 years).	Copy of GMP Certificate Ref. No. 100/2022-DRAP(AD-51001963034) dated 20-06-2022 valid for two years from the date of inspection (13-06-2022) has been submitted.
xiv.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	Cinaxipid Tablet 1mg, Axistart-K Tablets, Trubax Tablets etc.

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction / Typographical Mistake.**
- **Justification / clarification for points mentioned below;**
  - **2.3.P.5 USP recommends "Column: 4.6-mm × 5-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Dissolution Analysis.**
  - **2.3.P.5 USP recommends "Column: 3.2-mm × 25-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Assay / Content Uniformity.**
  - **2.3.P.5 Moreover, the Flow Rate and Injection volume are also different from that recommended in USP Monograph for Rosuvastatin Tablets.**
  - **2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.**

289.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 106/2020-DRAP(AD-1904818-970) dated 06-07-2020 valid for two years from the date of inspection (09-06-2020) has been submitted.
	Evidence of approval of manufacturing facility	Copy of letter for Renewal of DML vide No. F. 1-20/2006-Lic (Vol-II) dated 30th June, 2020 contains section approval for: - • **Tablet Section (General).** • Capsule Section (General). • Dry Powder Sachet Section (General). • Oral Liquid Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11997 dated 17 MAY 2022
	Details of fee submitted	PKR 30,000/- Dated 19-05-2022 (Challan / Receipt # 747783462)
	The proposed proprietary name / brand name	**AXITO 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Itopride Hydrochloride … 50mg (Innovator's Specifications)
	Pharmacotherapeutic Group of (API)	A03FA07, Drugs For Functional Gastrointestinal Disorders, Propulsives.
	Pharmaceutical form of applied drug	Round, biconvex, yellowish green colored film coated tablet, with both plain sides.
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PMDA Japan Approved.
	For generic drugs (me-too status)	GANATON 50mg Tablet by Abbott Laboratories (Pakistan) Ltd.
	Name and address of API manufacturer.	M/s Prayosha Healthcare Pvt. Ltd., Plot No. 6209 G.I.D.C Ankleshwar 393 002, Dist. Bharuch, Gujrat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against GANATON 50mg Tablet by Abbott Laboratories (Pakistan) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against GANATON 50mg Tablet by Abbott Laboratories (Pakistan) Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Prayosha Healthcare Pvt. Ltd., Gujrat, India.		
API Lot No.	ITP/004/21		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, (Months) Real Time: 0, 3, (Months)		
Batch No.	T-003	T-004	T-005
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	12-2021	12-2021	12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate issued by Food and Drugs Control Administration, Gujrat State, India has been submitted. The Certificate was **valid till 24/05/2023.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Clearance (vide No. 12557/2021 DRAP dated 20-08-2021) by AD I&E DRAP, Lahore has been submitted for 550Grams Itopride HCl Batch No. ITP/004/21 vide Invoice No. ZHI-Cl/5548/0821 dated 12-08-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail reports on product testing has been submitted. **Compliance Record of HPLC software 21CFR has not been submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

Deficiencies / Shortcomings	Response of the firm
i. Please confirm the name of Firm as it is mentioned as "M/s Axis Pharmaceuticals (Pvt.) Ltd." on enclosed copy of DML and on Renewal of your DML whereas the same is mentioned as "M/s Axis Pharmaceuticals" throughout your application. Please provide supporting documents for the same.	The firm has submitted correced copy of DML as "M/s Axis Pharmaceuticals".
ii. Finished Product Specifications have been claimed as per 'Innovator's Specifications', whereas in submitted Summary of Product Characteristics (SmPC) & Patient Information Leaflet (PIL) it is mentioned that "the product complies Axis's Specifications". Please clarify.	Typographic Mistake. Firm has submitted revised SmPC & PIL.
iii. Please provide valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed copy of GMP Certificate was valid till 24/05/2023.	Valid GMP of API Manufacturer has not been submitted.
iv. 2.3.P.3.2 The application has been claimed to be submitted for 'film coated tablet', whereas no ingredient for preparation of film coating has been mentioned in this section. Please clarify.	Firm has submitted revised Section 2.3.P.3.2 mentioning information regarding film coating.

v.	2.3.P.3.2 Appearance of the Tablet has been mentioned as 'light green colored film coated tablet', whereas the same has been mentioned as 'yellowish green colored film coated tablet' in Pharmaceutical Equivalence and CDP Studies. Please justify.	Typographic Mistake. Firm has stated that the appearance of product is 'light green colored film coated tablet'.
vi.	Dissolution specifications have been mentioned as 'NLT Q+5% in 30 mins' as well as 'NLT 80%(Q)' on separate instances within the application dossier. Please justify.	Firm has submitted that the Dissolution specifications is NLT 80% (Q) in 30 minutes.
vii.	Please provide 6th Month Data of Stability Batches, supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Copy of 6th Month Data of Stability Batches has been submitted.
viii.	Please provide Compliance Record of HPLC Software 21CFR.	Certificate of 21CFR Compliance of HPLC Software has not been submitted.
ix.	Please provide GMP status of the FPP manufacturer (not older than 03 years).	Copy of GMP Certificate Ref. No. 100/2022-DRAP(AD-51001963034) dated 20-06-2022 valid for two years from the date of inspection (13-06-2022) has been submitted.
x.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	Cinaxipid Tablet 1mg, Axistart-K Tablets, Trubax Tablets etc.

Decision: Registration Board deferred the case for submission of:

- **Full fee for pre-registration correction / Typographical Mistakes.**
- **Justification / clarification for points mentioned below;**
  - **2.3.P.3.2 The application has been claimed to be submitted for 'film coated tablet', whereas no ingredient for preparation of film coating has been mentioned in this section.**
  - **2.3.P.3.2 Appearance of the Tablet has been mentioned as 'light green colored film coated tablet', whereas the same has been mentioned as 'yellowish green colored film coated tablet' in Pharmaceutical Equivalence and CDP Studies.**
  - **Dissolution specifications have been mentioned as 'NLT Q+5% in 30 mins' as well as 'NLT 80%(Q)' on separate instances within the application dossier.**
  - **Please provide 6th Month Data of Stability Batches, supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.**

290.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Obsons Pharmaceuticals, 209-S Industrial Estate, Kotlakhpat, Lahore.**
	Name, address of Manufacturing site.	M/s Obsons Pharmaceuticals, 209-S Industrial Estate, Kotlakhpat, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 15/2022-DRAP(AD-1094225483) dated 07-03-2022 valid for two years from the date of inspection (22-02-2022) has been submitted.
	Evidence of approval of manufacturing facility	Copy of GMP Certificate Ref. No. 15/2022-DRAP(AD-1094225483) dated 07-03-2022 valid for two years from the

		date of inspection (22-02-2022) has been submitted, mentioning the following sections: - • **Capsule Section (General)** • Tablet Section (General) • Oral Liquid Section (General) • Dry Powder Suspension Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23519 dated 19 AUG 2022
	Details of fee submitted	PKR 30,000/- Dated 16-06-2022 (Challan / Receipt # 7381624292)
	The proposed proprietary name / brand name	**E-ZOLE 20mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Enteric coated pellets of Esomeprazole magnesium trihydrate equivalent to Esomeprazole … 20mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	A02BC05, Proton pump inhibitors.
	Pharmaceutical form of applied drug	White enteric coated pellets filled in Purple colored hard gelatin capsule shell.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NEXIUM 20mg Capsules, USFDA Approved.
	For generic drugs (me-too status)	NEXUM 20mg Capsules by M/s Getz Pharma (Pvt) Ltd.
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C /

		75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against NEXUM 20mg Capsules by M/s Getz Pharma (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against NEXUM 20mg Capsules by M/s Getz Pharma (Pvt) Ltd.in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road Islamabad.		
API Lot No.	EMZ045893		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	099	123	129
Batch Size	70,000 Capsules	70,000 Capsules	70,000 Capsules
Manufacturing Date	10-2019	11-2019	11-2019
Date of Initiation	14-11-2019	20-11-2019	26-11-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate No. F.3-26/2019-Addl. Dir.(QA&LT-I) dated 31st July 2019 valid for three years from the date of inspection (11th February 2019) has been submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 600494 dated 26/08/19 for local purchase of 29Kgs Esomeprazole Magnesium EC Pellets 10.5%, Batch No.

		EMZ045893, from M/s Vision Pharma, Islamabad has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers (**January to June 2021**).

Remarks of Evaluator:

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

i. 1.5.8 Reference in this section has been mentioned as "***Generic Name: Diclofenac Potassium -50*****".** Please justify.

ii. 3.S.4.3 a) Summary of the validation information, it has been mentioned that "***Diclofenac Potassium API*** *is tested as per USP Monograph".* Please justify.

iii. 2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.

iv. 2.3.P.3.2 Batch Formula, the strength (label claim) has been mentioned as *"Each Hard Gelatin Capsule contain:* ***Esomeprazole Magnesium Trihydrate …20mg****"*, which is not as per Innovator / Reference. Please justify.

v. 2.3.P.3.2 Batch Formula, API in this section has been mentioned as ***Levofloxacin Hemihydrate 13.77Kg/Batch***. Please justify.

vi. 2.3.P.5.2 a) Summary of Analytical Procedures, USP Dissolution (Test -4) recommends Temperatures as "*Autosampler: 5° & Column: 30°, Flow rate: 1.2 mL/min and Injection volume: 15 µL*" whereas the applicant has mentioned "*Temperature: Ambient, Flow rate: 1 mL/min and Injection volume: 20 µL*". Please justify.

vii. 3.2.P.2.2.1 (b) i. Pharmaceutical Equivalence & Comparative Dissolution Profile has been submitted for **Obpra 20mg Capsules, Batch No. 314**, which is not the applied Drug Product. Please justify.

viii. Furthermore, please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.

ix. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) has been submitted from **January to June 2021** only, whereas the Stability Study was commenced in the year 2019. Please clarify.

x. 3.2.P.5.1 Control of Drug Product Specifications have been mentioned as "**In-house Specs**" in SOP No: QC/SOP/RMA/E04, Effective Date 07-Sep 2020, whereas the same have been claimed as per 'USP Specifications' in application dossier. Please clarify.

xi. Process Validation Protocol, Specifications of Drug Product, Analytical Procedures & Verification and Stability Study Data / BMRs have been submitted for "**Obpra 20mg Capsules",** which is not the applied Drug Product. Please justify.

xii.	Please provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	
xiii.	Please provide valid approval of API/ DML/GMP Certificate of API manufacturer. The enclosed copy of GMP Certificate was valid till February, 2022.	
xiv.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
291.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Obsons Pharmaceuticals, 209-S Industrial Estate, Kotlakhpat, Lahore.**
	Name, address of Manufacturing site.	M/s Obsons Pharmaceuticals, 209-S Industrial Estate, Kotlakhpat, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 15/2022-DRAP(AD-1094225483) dated 07-03-2022 valid for two years from the date of inspection (22-02-2022) has been submitted.
	Evidence of approval of manufacturing facility	Copy of GMP Certificate Ref. No. 15/2022-DRAP(AD-1094225483) dated 07-03-2022 valid for two years from the date of inspection (22-02-2022) has been submitted, mentioning the following sections: - • **Capsule Section (General)** • Tablet Section (General) • Oral Liquid Section (General) • Dry Powder Suspension Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23520 dated 19 AUG 2022
	Details of fee submitted	PKR 30,000/- Dated 16-06-2022 (Challan / Receipt # 482537264051)
	The proposed proprietary name / brand name	**E-ZOLE 40mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Enteric coated pellets of Esomeprazole magnesium trihydrate equivalent to Esomeprazole … 40mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	A02BC05, Proton pump inhibitors.
	Pharmaceutical form of applied drug	White enteric coated pellets filled in Purple colored hard gelatin capsule shell.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NEXIUM 40mg Capsules, USFDA Approved.
	For generic drugs (me-too status)	NEXUM 40mg Capsules by M/s Getz Pharma (Pvt) Ltd.

	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against NEXUM 40mg Capsules by M/s Getz Pharma (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against NEXUM 40mg Capsules by M/s Getz Pharma (Pvt) Ltd.in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road Islamabad.
API Lot No.	EMZ045482
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 Months Accelerated: 6 Months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	101	119	131
Batch Size	70,000 Capsules	70,000 Capsules	70,000 Capsules
Manufacturing Date	10-2019	11-2019	11-2019
Date of Initiation	15-11-2019	23-11-2019	29-11-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate No. F.3-26/2019-Addl. Dir.(QA&LT-I) dated 31st July 2019 valid for three years from the date of inspection (11th February 2019) has been submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 402575 dated 08/05/18 for local purchase of 25Kgs Esomeprazole Magnesium EC Pellets 22.5%, Batch No. EMZ045482, from M/s Vision Pharma, Islamabad has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers (**January to June 2021**).

Remarks of Evaluator:

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

i. 1.5.8 Reference in this section has been mentioned as "***Generic Name: Diclofenac Potassium -50*****".** Please justify.

ii. 3.S.4.3 a) Summary of the validation information, it has been mentioned that "***Diclofenac Potassium API*** *is tested as per USP Monograph".* Please justify.

iii. 2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.

iv. 2.3.P.1 (b) Composition of the Drug Product, the strength (label claim) has been mentioned as **20mg.** Please justify.

v. 2.3.P.3.2 Batch Formula, the strength (label claim) has been mentioned as *"Each Hard Gelatin Capsule contain:* ***Esomeprazole Magnesium Trihydrate …40mg****"*, which is not as per Innovator / Reference. Please justify.

vi. 2.3.P.3.2 Batch Formula, API in this section has been mentioned as ***Levofloxacin Hemihydrate 12.53Kg/Batch***. Please justify.

vii. 2.3.P.5.2 a) Summary of Analytical Procedures, USP Dissolution (Test -4) recommends Temperatures as "*Autosampler: 5° & Column: 30°, Flow rate: 1.2 mL/min and Injection volume: 15 µL*" whereas the applicant has mentioned "*Temperature: Ambient, Flow rate: 1 mL/min and Injection volume: 20 µL*". Please justify.

viii. 3.2.P.2.2.1 (b) i. Pharmaceutical Equivalence & Comparative Dissolution Profile has been submitted for **Obpra 40mg Capsules, Batch No. 332**, which is not the applied Drug Product. Please justify.

ix. Furthermore, please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.

x. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) has been submitted from **January to June 2021** only, whereas the Stability Study was commenced in the year 2019. Please clarify.

xi. 3.2.P.5.1 Control of Drug Product Specifications have been mentioned as "**In-house Specs**" in SOP No: QC/SOP/RMA/E03, Effective Date 07-Sep 2020, whereas the same have been claimed as per 'USP Specifications' in application dossier. Please clarify.

xii. Process Validation Protocol, Specifications of Drug Product, Analytical Procedures & Verification and Stability Study Data / BMRs have been submitted for "**Obpra 40mg Capsules",** which is not the applied Drug Product. Please justify.

xiii. Please provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

xiv. Please provide valid approval of API/ DML/GMP Certificate of API manufacturer. The enclosed copy of GMP Certificate was valid till February, 2022.

xv. Please provide Reference of previous approval of applications with stability study data of the firm (if any).

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

292.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Obsons Pharmaceuticals, 209-S Industrial Estate, Kotlakhpat, Lahore.**
	Name, address of Manufacturing site.	M/s Obsons Pharmaceuticals, 209-S Industrial Estate, Kotlakhpat, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 15/2022-DRAP(AD-1094225483) dated 07-03-2022 valid for two years from the date of inspection (22-02-2022) has been submitted.
	Evidence of approval of manufacturing facility	Copy of GMP Certificate Ref. No. 15/2022-DRAP(AD-1094225483) dated 07-03-2022 valid for two years from the date of inspection (22-02-2022) has been submitted, mentioning the following sections: - • Capsule Section (General) • **Tablet Section (General)** • Oral Liquid Section (General) • Dry Powder Suspension Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23517 dated 19 AUG 2022
	Details of fee submitted	PKR 30,000/- Dated 09-06-2022 (Challan / Receipt # 36759826)
	The proposed proprietary name / brand name	**NO-HISTA 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Levocetirizine Dihydrochloride …5mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	R06AE09, Antihistamines For Systemic Use
	Pharmaceutical form of applied drug	White, Round, Film Coated Tablet, Plain on both sides.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XYZAL 5mg Tablet, USFDA Approved (Discontinued, **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**).
	For generic drugs (me-too status)	NEO-SEDIL 5mg Tablets of M/s SAMI Pharmaceuticals (Pvt.) Limited.
	Name and address of API manufacturer.	M/s HEMA Pharmaceuticals Pvt. Ltd, Plot No. 620, GIDC, Ankleshwar, Gujarat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against T-Day 5mg Tablets by M/s GSK by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against T-Day 5mg Tablets by M/s GSK in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s HEMA Pharmaceuticals Pvt. Ltd, India.		
API Lot No.	18LV0015		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19B027	933	117
Batch Size	41,000 Tablets	500,000 Tablets	100,000 Tablets
Manufacturing Date	02-2019	02-2019	02-2019
Date of Initiation	06-03-2019	04-03-2019	12-12-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate No. S-GMP/1805813 issued by Food & Drugs Control Administration, Gandhinagar, Gujrat State, valid from 09/05/2018 to 08/05/2020 has been submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. ZHI-CI/3212/1118 dated 26-11-2018 for import of 25Kgs Levocitirizine Dihydrochloride, Batch No. 18LV0015, Cleared by AD (I&E) Lahore, vide No. 15589/2018-DRAP dated 3-12-18 has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers (**January to June 2021**).

Remarks of Evaluator:

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

i. 1.5.14 Prescribing Information Leaflet has been submitted for **Levortizin** 5mg Tablet, which is not the applied drug product. Please clarify.

ii. Please provide valid approval of API/ DML/GMP Certificate of API manufacturer. The enclosed copy of GMP Certificate was valid till 08/05/2020.

iii. 2.3.S.4.4 Submitted COA of API from the drug product manufacturer mentions the API Manufacturer as 'MAPS Laboratories, India' whereas the same has been mentioned as 'M/s HEMA Pharmaceuticals Pvt. Ltd, India' in rest of the dossier application. Please justify.

iv. 3.2.S.4.1 Drug Substance Specifications by API Manufacturer claims the Drug Substance to be of "In-House Grade" (Specification No. FPS/LCB-01, Effective Date: 08/06/2014) whereas Levocetirizine Dihydrochloride Monograph is available in USP. Please justify.

v. 3.2.P.2.2.1 (b) i. Pharmaceutical Equivalence & Comparative Dissolution Profile has been submitted for **Levortizin 5mg Tablet, Batch No. 192**, which is not the applied Drug Product. Please justify.

vi. Furthermore, please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.

vii. 3.2.P.8.2 Stability Protocol for Commitment Batches, Acceptance Criteria for Identification Test has been mentioned as *"The retention time of the **diclofenac peak** of solution sample corresponds to standard solution, in the assay".* Please justify.

viii. Process Validation Protocol, Specifications of Drug Product, Analytical Procedures & Verification and Stability Study Data / BMRs have been submitted for "**Levortizin 5mg Tablet",** which is not the applied Drug Product. Please justify.

ix. The Total No. of units of Stability / Product Development / Validation Batches is more than 600,000 Units. Please clarify, what would be the fate of these units / batches.

x. Please provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

xi. Please provide Reference of previous approval of applications with stability study data of the firm (if any).

xii. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) has been submitted from **January to June 2021** only, whereas the Stability Study was commenced in the year 2019. Please clarify.

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

293.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Obsons Pharmaceuticals, 209-S Industrial Estate, Kotlakhpat, Lahore.**
	Name, address of Manufacturing site.	M/s Obsons Pharmaceuticals, 209-S Industrial Estate, Kotlakhpat, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 15/2022-DRAP(AD-1094225483) dated 07-03-2022 valid for two years from the date of inspection (22-02-2022) has been submitted.
	Evidence of approval of manufacturing facility	Copy of GMP Certificate Ref. No. 15/2022-DRAP(AD-1094225483) dated 07-03-2022 valid for two years from the

		date of inspection (22-02-2022) has been submitted, mentioning the following sections: - • **Capsule Section (General)** • Tablet Section (General) • Oral Liquid Section (General) • Dry Powder Suspension Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24365 dated 29 AUG 2022
	Details of fee submitted	PKR 30,000/- Dated 11-08-2022 (Challan / Receipt # 01183517)
	The proposed proprietary name / brand name	**OBCAM 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard gelatin capsule contains: Piroxicam …20mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	M01AC01, Anti-inflammatory And Anti-rheumatic Products, Non-Steroids.
	Pharmaceutical form of applied drug	White powder filled in capsule shell.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	FELDENE 20mg Capsules, USFDA Approved.
	For generic drugs (me-too status)	FELDENE 20mg Capsules of M/s Pfizer Pakistan Limited.
	Name and address of API manufacturer.	M/s Alcon Biosciences Pvt. Ltd, A-1/2104m, Phase-III G.I.D.C VAPI – 396 195, Dist. – Valsad, Gujarat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 60 Months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against T-Day 5mg Tablets by M/s GSK by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against T-Day 5mg Tablets by M/s GSK in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Alcon Biosciences Pvt. Ltd, India.		
API Lot No.	PCM/1027/20		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19K141	19K146	19K151
Batch Size	50,000 Capsules	50,000 Capsules	50,000 Capsules
Manufacturing Date	11-2019	11-2019	11-2019
Date of Initiation	06-11-2019	15-11-2019	28-11-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate No. S-GMP/20102297 issued by Food & Drugs Control Administration, Gandhinagar, Gujrat State, valid from 22/10/2020 to 21/10/2022 has been submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. AV/1/00032/20-21 dated 23-05-2020 for import of 50Kgs Piroxicam BP, Batch No. PCM-1027/20, Cleared by AD (I&E) Lahore, vide No. 8621/2020-DRAP dated 03-07-2020 has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers (**January to June 2021**).

Remarks of Evaluator:

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

i. Please provide valid approval of API/ DML/GMP Certificate of API manufacturer. The enclosed copy of GMP Certificate was valid till 21/10/2022.

ii. 3.2.S.4.1 Drug Substance Specifications by API Manufacturer claims the Drug Substance to be of "USP Specifications" throughout the application dossier, whereas the Certificate of Analysis of relevant Batch (PCM-1027/20) enclosed in 3.2.S.4.4(a) shows that the API 'Piroxicam BP, complies with prescribed specifications as per BP-2018". Please justify.

iii. 3.2.P.1(d) Type of container closure system used for the FPP, it has been mentioned that the '**Ob-flox 500mg Tablet**' are packed in Alu-PVC. Please clarify.

iv. 3.2.P.2.2.1 (b) i. Pharmaceutical Equivalence & Comparative Dissolution Profile has been submitted for **Vincam 20mg Capsule, Batch No. 21J199**, which is not the applied Drug Product. Please justify.

v. Furthermore, please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.

vi. 3.2.P.5.2 Analytical Procedure, SOP No. QC/SOP/FP/V01, Effective Date 07-Sep 2020, Column used for Assay has been mentioned as 'Column: 4.6-mm × 25-cm; packing L1' whereas USP in its Monograph for Piroxicam Capsules recommends Column: **3.9-mm × 30-cm**; packing L1. Please justify.

vii. 3.2.P.8.2 Stability Protocol for Commitment Batches, Acceptance Criteria for Description Test has been mentioned as '**Yellow color oblong film coated tablet'** whereas the same has been mentioned as '**Yellow color oblong film coated Capsules**' in 2.3.P.8.2. Please justify.

viii. Process Validation Protocol, Specifications of Drug Product, Analytical Procedures & Verification and Stability Study Data / BMRs have been submitted for "**Vincam 20mg Capsule",** which is not the applied Drug Product. Please justify.

ix. Documents for the procurement of relevant batch of API (PCM/1027/20) with approval from DRAP show that the **material was cleared in July 2020**, whereas the Stability Study of submitted batches was commenced in **November 2019**. Please justify.

x. The Total No. of units of Stability / Product Development / Validation Batches is around 150,000 Units. Please clarify, what would be the fate of these units / batches.

xi. Please provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

xii. Please provide Reference of previous approval of applications with stability study data of the firm (if any).

xiii. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) has been submitted from **January to June 2021** only, whereas the Stability Study was commenced in the year 2019. Please clarify.

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

294.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate No. 38/2021-DRAP(K) dated 09th September 2021 valid for two years from the date of inspection (03-09-2021) has been submitted.
	Evidence of approval of manufacturing facility	Copy of GMP Certificate No. 38/2021-DRAP(K) dated 09th September 2021 valid for two years from the date of inspection (03-09-2021) has been submitted, mentioning Tablet (General) Section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25517 dated 08 SEP 2022
	Details of fee submitted	PKR 75,000/- Dated 15-08-2022 (Challan / Receipt # 61705973164)
	The proposed proprietary name / brand name	**TRANEXA 650mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Tranexamic Acid … 650mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	B02AA02, Anti-fibrinolytics, Amino acids.
	Pharmaceutical form of applied drug	White oblong tablet, plain on both sides.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYSTEDA 650mg Tablets, USFDA Approved.
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Hunan Dongting Pharmaceutical Co., Ltd., No. 16 Dongyan Road, Dehan, Changde, PC415001, Hunan Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 72 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against LYSTEDA 650mg Tablets by M/s Ferring Pharmaceuticals. Firm has submitted CDP results of their product against LYSTEDA 650mg Tablets by M/s Ferring Pharmaceuticals in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Hunan Dongting Pharmaceutical Co., Ltd., China.		
API Lot No.	X2010609M		
Description of Pack (Container closure system)	HDPE Bottles		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1000 Tablets	700 Tablets	800 Tablets
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	03-2021	03-2021	03-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate No. HN20160173 issued by China Food and Drug Administration, valid until 31/01/2021 has been submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 00459014 dated Dec.07,2020 for import of 5Kgs Tranexamic Acid JP17, Batch No. X2010609M has been submitted. **However approval from DRAP for import of above has not been submitted.**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers (**December 2021 to July 2022**).

Remarks of Evaluator:

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

Deficiencies / Shortcomings	Response of the firm
i. Please provide valid approval of API/ DML/GMP Certificate of API manufacturer. The enclosed copy of GMP Certificate was valid till 31/01/2021.	Copy of GMP Certificate No. HA20190077 issued by CFDA valid until 05-11-2024 has been submitted.
ii. 2.3.P.8.1 Dissolution results have been obtained >100% (up to 107%) in each time point tested for all 03 Trial Batches which is an indication that either there's a problem with the dissolution of the product or the uniformity of dosage units or both. Please justify with supporting evidences.	The firm have submitted that the presence of Sodium Lauryl Sulfate tends to slightly elevate dissolution results, exceeding 100-110% for a BCS Class 1 mollecule are frequently enclountered.
iii. 3.2.S.4. Analytical Method Verification Report for 'Tranexamic Acid USP' by Finished Product Manufacturer has been submitted for Assay Procedure based on Titration Method, whereas USP Monograph for Tranexamic Acid recommends Assay analysis based on HPLC Method. Please justify.	The firm have submitted that until April 2021, the USP specified the assay using a titration method. However, with the official version introduced after May 2021, there was a shift in the assay method from Titration to HPLC method.
iv. The API 'Tranexamic Acid' as evident from Import Documents is of 'JP Specs", whereas the information submitted in Substance Part of CTD Application claims that the API is of 'EP/BP Specs' and Finished Product Manufacturer has claimed that the API has been tested as per 'USP Specs". Please justify with supporting evidences.	Typographical error. Drug Substance Manufacturer has performed test as per JP Specifications whereas Kaizen Pharma conducted API testing using USP test method as majority of tests outlined in USP encompass and fulfil the requirements as specified in th JP, ensuring comprehensive evaluation and compliance.

v.	3.2.P.5.2 USP in its monograph for Tranexamic Acid Tablets recommends 'Column: 4.6-mm × 10-cm; 3.5-µm packing L1' for Assay & Dissolution Analysis whereas as you have used 'Column: 4.6-mm × 10-cm; 3.5-µm packing C18'. Please justify.	The firm have submitted that the L series designation in the USP lisiting procedure for HPLC columns indicate that both L1 and C18 refer to the same type of column.
vi.	3.2.P.5.2 Please specify the Dissolution Test 1 or 2.	The firm have used USP Test-1 for dissolution method.
vii.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) has been submitted from **December 2021 to July 2022**, whereas the Stability Study was commenced in **March 2021**. Please clarify.	Additional data have been submitted.
viii.	Please provide approval from DRAP for import of 5Kgs Tranexamic Acid JP17, Batch No. X2010609M vide Invoice No. 00459014 dated Dec.07,2020.	Copy of AD(I&E), DRAP Karachi attested Invoice vide No. 14280/2020 dated 21 DEC 2020 has been submitted.
ix.	Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.	Submitted.
x.	Please provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted.
xi.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	Rofair (Roflumilast) 500mcg Tablet.

Decision: Approved. The firm shall submit following before issuance of registration letter:

(i) Analytical Method Verification Studies on HPLC and

(ii) Requisite fee for pre-registration correction / Typographical Mistake

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

295.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories (Pvt.) Ltd., 16-Km Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories (Pvt.) Ltd., 16-Km Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Copy of GMP Certificate Ref. No. 93/2020-DRAP(AD-2003099-790) dated 09-06-2020 valid for two years from the date of inspection (04-02-2020) has been submitted.
	Evidence of approval of manufacturing facility	Copy of GMP Certificate Ref. No. 93/2020-DRAP(AD-2003099-790) dated 09-06-2020 valid for two years from the date of inspection (04-02-2020) has been submitted, mentioning Tablet (Non-Antibiotic, Antibiotic, Psychotropic, Cephalosporin & Ani-Cancer) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26719 dated 21 SEP 2022
	Details of fee submitted	PKR 30,000/- Dated 06-09-2022 (Challan / Receipt # 19839887999)
	The proposed proprietary name / brand name	**ELSART 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Telmisartan … 40mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	C09CA07, Angiotensin II receptor blockers (ARBs), plain.
	Pharmaceutical form of applied drug	White oval shaped, biconvex core tablet plain from both sides.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Telmisartan 40mg Tablets of M/s Brillpharma (Ireland) Limited, Health Products Regulatory Authority (Ireland) Approved.
	For generic drugs (me-too status)	TASMI Tablets 40mg of M/s Getz Pharma (Pvt.) Limited.
	Name and address of API manufacturer.	M/s Jiangsu Zhongbang Pharmaceutical Co., Ltd. 36 Shuanggao Rd., Gaochun, Nanjin, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches of drug

	(Conditions & duration of Stability studies)	substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against TASMI Tablets 40mg of M/s Getz Pharma (Pvt.) Limited by performing quality tests (Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against TASMI Tablets 40mg of M/s Getz Pharma (Pvt.) Limited in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangsu Zhongbang Pharmaceutical Co., Ltd. China.		
API Lot No.	D10011-20190905		
Description of Pack (Container closure system)	Alu-PVC Blisters		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TEL40-SB001	TEL40-SB002	TEL40-SB003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	12-2021	01-2022	01-2022
Date of Initiation	09-02-2022	09-02-2022	09-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of Notice of GMP Inspect results of Jiangsu Province No.83/2020 has been enclosed.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. YST19187C dated Dec.19,2019 for import of 4Kgs Telmisartan, cleared by AD(I&E) Lahore vide No. 2399/2020-DRAP dated 14-02-2020, has been submitted.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports on product testing. **However, Compliance Record of HPLC software 21CFR has not been submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

	Deficiencies / Shortcomings	Response of the firm
i.	Please provide valid GMP status of the firm (FPP Manufacturer). The enclosed copy of GMP Certificate was valid for two years from the date of inspection (04-02-2020).	The firm have submitted that they have applied for renewal of GMP and are waiting for Inspection.
ii.	Please provide valid evidence of approval of manufacturing facility issued by concerned division (Section approval letter).	Section approval letter has not been submitted.
iii.	Please provide valid approval of API/ DML/GMP Certificate of API manufacturer issued by concerned Regulatory Authority of Country of Origin.	GMP Certificate of API manufacturer issued by concerned Regulatory Authority of Country of Origin has not been submitted.
iv.	Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.	Submitted.
v.	3.2.P.5.2 Please specify the Dissolution Test 1, 2 or 3.	The firm has mentioned that they have used Dissolution Test 1. Furthermore, the firm have submitted Revised Method of Analysis for Elsart 40mg and 80mg Tablets.
vi.	3.2.P.5.3 Analytical Method has been verified vide Verification Report No. QC/AMV/R/033-01, Effective Date March, 2022, whereas Stability Study was commenced (Initial Testing) in 12-2021 for TEL40-SB001 and 01-2022 for TEL40-SB002 & TEL40-SB003. Please justify.	The firm have submitted that due to unavailability of Reference standard, they were unable to perform verification studies initially, once received, they performed verification studies before third month testing of product on stability.
vii.	3.2.P.5.3 USP in its monograph for Telmisartan Tablets recommends 'Column: 4.0-mm × 4-cm; 5-µm packing L1, Flow rate: 0.7 mL/min' for Assay Analysis whereas you have used 'Column: 4.6-mm × 2.5-cm; 10-µm packing C18', Flow rate: 0.5 mL/min'. Please justify.	The firm have submitted Revised Method of Analysis for Elsart 40mg and 80mg Tablets.

viii.	3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.	Submitted.
ix.	Description of Pack (Container closure system) has been mentioned as 'Alu-PVC Blisters' as well as 'Alu-Alu Blisters' on separate instances within the application dossier. Please clarify.	Typographical error. Container closure system is 'Alu-Alu Blisters'.
x.	Please provide Compliance Record of HPLC software 21CFR.	Submitted.
xi.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	VONOV 10mg and 20mg Tablets.

Decision: Registration Board deferred the case for submission of:

- **Relevant documents as required for points (i) (ii) and (iii) mentioned above.**
- **Data of submitted batches as per revised Method of Analysis.**
- **Fee of 7500/ will be submitted correction / Typographical Mistake**

296.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories (Pvt.) Ltd., 16-Km Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories (Pvt.) Ltd., 16-Km Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 93/2020-DRAP(AD-2003099-790) dated 09-06-2020 valid for two years from the date of inspection (04-02-2020) has been submitted.
	Evidence of approval of manufacturing facility	Copy of GMP Certificate Ref. No. 93/2020-DRAP(AD-2003099-790) dated 09-06-2020 valid for two years from the date of inspection (04-02-2020) has been submitted, mentioning Tablet (Non-Antibiotic, Antibiotic, Psychotropic, Cephalosporin & Ani-Cancer) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26718 dated 21 SEP 2022
	Details of fee submitted	PKR 30,000/- Dated 06-09-2022 (Challan / Receipt # 77086083419)
	The proposed proprietary name / brand name	**ELSART 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Telmisartan … 80mg

		(USP Specifications)
	Pharmacotherapeutic Group of (API)	C09CA07, Angiotensin II receptor blockers (ARBs), plain.
	Pharmaceutical form of applied drug	White round shaped, biconvex core tablet plain from both sides.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Telmisartan 80mg Tablets of M/s Brillpharma (Ireland) Limited, Health Products Regulatory Authority (Ireland) Approved.
	For generic drugs (me-too status)	TASMI Tablets 80mg of M/s Getz Pharma (Pvt.) Limited.
	Name and address of API manufacturer.	M/s Jiangsu Zhongbang Pharmaceutical Co., Ltd. 36 Shuanggao Rd., Gaochun, Nanjin, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against TASMI Tablets 80mg of M/s Getz Pharma (Pvt.) Limited by performing quality tests (Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against TASMI Tablets 80mg of M/s Getz Pharma (Pvt.) Limited in 03 dissolution media.
	Analytical method validation/verification of	Method verification / validation studies have been submitted

	product	for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangsu Zhongbang Pharmaceutical Co., Ltd. China.		
API Lot No.	D10011-20190905		
Description of Pack (Container closure system)	Alu-PVC Blisters		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TEL80-SB001	TEL80-SB002	TEL80-SB003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	11-2021	01-2022	01-2022
Date of Initiation	09-02-2022	09-02-2022	09-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of Notice of GMP Inspect results of Jiangsu Province No.83/2020 has been enclosed.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. YST19187C dated Dec.19,2019 for import of 4Kgs Telmisartan, cleared by AD(I&E) Lahore vide No. 2399/2020-DRAP dated 14-02-2020, has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports on product testing. **However, Compliance Record of HPLC software 21CFR has not been submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

Deficiencies / Shortcomings	Response of the firm
i. Please provide valid GMP status of the firm (FPP Manufacturer). The enclosed copy of GMP Certificate was valid for two years from the date of inspection (04-02-2020).	The firm have submitted that they have applied for renewal of GMP and are waiting for Inspection. Section approval letter has not been submitted.

ii.	Please provide valid evidence of approval of manufacturing facility issued by concerned division (Section approval letter).	
iii.	Please provide valid approval of API/ DML/GMP Certificate of API manufacturer issued by concerned Regulatory Authority of Country of Origin.	GMP Certificate of API manufacturer issued by concerned Regulatory Authority of Country of Origin has not been submitted.
iv.	Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.	Submitted.
v.	3.2.P.5.2 Please specify the Dissolution Test 1, 2 or 3.	The firm has mentioned that they have used Dissolution Test 1. Furthermore, the firm have submitted Revised Method of Analysis for Elsart 40mg and 80mg Tablets.
vi.	3.2.P.5.3 Analytical Method has been verified vide Verification Report No. QC/AMV/R/033-01, Effective Date March, 2022, whereas Stability Study was commenced (Initial Testing) in 11-2021 for TEL80-SB001 and 01-2022 for TEL80-SB002 & TEL80-SB003. Please justify.	The firm have submitted that due to unavailability of Reference standard, they were unable to perform verification studies initially, once received, they performed verification studies before third month testing of product on stability.
vii.	3.2.P.5.3 USP in its monograph for Telmisartan Tablets recommends 'Column: 4.0-mm × 4-cm; 5-µm packing L1, Flow rate: 0.7 mL/min' for Assay Analysis whereas you have used 'Column: 4.6-mm × 2.5-cm; 10-µm packing C18', Flow rate: 0.5 mL/min'. Please justify.	The firm have submitted Revised Method of Analysis for Elsart 40mg and 80mg Tablets.
viii.	3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.	Submitted.
ix.	Description of Pack (Container closure system) has been mentioned as 'Alu-PVC Blisters' as well as 'Alu-Alu Blisters' on separate instances within the application dossier. Please clarify.	Typographical error. Container closure system is 'Alu-Alu Blisters'.
x.	Please provide Compliance Record of HPLC software 21CFR.	Submitted.
xi.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	VONOV 10mg and 20mg Tablets.

Decision: Registration Board deferred the case for submission of: • **Relevant documents as required for points (i) (ii) and (iii) mentioned above.** • **Data of submitted batches as per revised Method of Analysis.** • **Fee of 7500/ will be submitted correction / Typographical Mistake**		
297.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mass Pharma (Pvt.) Ltd., 17-Km, Ferozepur Road, Lahore.**
	Name, address of Manufacturing site.	M/s Mass Pharma (Pvt.) Ltd., 17-Km, Ferozepur Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 149/2020-DRAP(FID-1991444-228) dated 14-12-2020 valid for two years from the date of inspection (23-09-2020) has been submitted.
	Evidence of approval of manufacturing facility	Copy of DML Renewal vide Letter No. F.1-4/96-Lic(Vol-I) dated 14th October 2021 mentioning **Oral Dry Powder Suspension Section (Cephalosporin)** has been submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27125 dated 26 SEP 2022
	Details of fee submitted	PKR 30,000/- Dated 08-09-2022 (Challan / Receipt # 92571653)
	The proposed proprietary name / brand name	**SPRIL DS 200mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cefixime (as Cefixime Trihydrate) … 200mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	J01DD08, Third-generation cephalosporins.
	Pharmaceutical form of applied drug	For Oral Suspension
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	30ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SUPRAX 200mg/5ml For Oral Suspension (USFDA Approved).
	For generic drugs (me-too status)	CEFSPAN DS Suspension 200mg/5ml of M/s Barrett Hodgson Pakistan (Pvt) Ltd.
	Name and address of API manufacturer.	M/s Pharmagen Ltd., Kot Nabi Bukhsh Wala, 34-Km, Ferozpur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability

		studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against CARICEF Suspension DS, Batch No. 015H of Sami Pharmaceuticals by performing quality tests (pH and Assay).
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Ltd., Lahore.		
API Lot No.	00243/108/2021		
Description of Pack (Container closure system)	Amber Glass Bottle, 30ml.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	SPS-01-22	SPS-02-22	SPS-03-22
Batch Size	100 Bottles	100 Bottles	100 Bottles
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	01-2022	01-2022	01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate Ref. No. 129/2020-DRAP(AD/1998630-530) dated 02-09-2020 valid for two years from the date of inspection (22-06-2020) has been submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. PL/P-INV/HO/405 dated 07/10/2021 for Local Purchase of 25Kgs Cefixime (Micronized) has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports on product testing. **However certificate of 21CFR compliance of HPLC software has not been submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

	Deficiencies / Shortcomings	Response of the firm
i.	1.5.2 Please correct the label claim as 'Each 5ml reconstituted suspension contains: Cefixime (as Cefixime Trihydrate) … 200mg'.	The firm have corrected label claim as: 'Each 5ml reconstituted suspension contains: Cefixime (as Cefixime Trihydrate) … 200mg'.
ii.	Please provide valid GMP status of the firm (FPP Manufacturer), the enclosed GMP Certificate was valid for two years from the date of inspection (23-09-2020).	The firm have submitted copy of GMP Certificate Ref. No. 80/2023-DRAP(AD-279945131777-531) dated 23-05-2023 valid for two years from the date of Inspection (19-05-2023).
iii.	1.5.9 The status in reference regulatory authority has been referred to 'NDA No. 202091 of Lupin Pharmaceuticals Inc., USFDA". However, the referred NDA Number is of '500mg/5ml for Suspension' whereas the application is of '200mg/5ml for Suspension'. Please clarify / provide relevant reference.	**Typographical Error.** NDA No. 065355
iv.	1.5.14 a) In Section P.1.C.5.1 as well as Section 2.3.P.3.2 the strength has been mentioned as **100mg/5ml**. Please justify.	**Typographical Error.**
v.	P.1C.5.4.2 It has been mentioned that 'after reconstitution, the suspension may be kept for 14 days either at room temperature, or under, Refrigeration. **Discard portion after 14 days**'. Whereas, in section P.1.C.5.6.4 Special precautions for storage has been mentioned as 'Reconstituted suspension should be stored at 2℃ to 8℃ for upto **7 days**'. Please clarify and submit supporting data (In-use stability studies).	**Typographical Error.** 'After reconstitution, the suspension may be kept for 07 days at room temperature, or under, Refrigeration for upto 14 days.

vi.	2.3.S.4.1 Specifications of the Drug Substance have been claimed as per 'USP Specs' whereas the COA enclosed for Batch No. 00243/108/2021 is as per 'BP Specs'. Please justify.	The firm have submitted that they have tested the said Batch as per USP Specifications and it complies as per USP Specifications.
vii.	2.3.P.2.2.1 b) It has been mentioned that 'Pharmaceutical Equivalence was performed against innovator pack i.e. **CEFSPAN** Suspension (Manufactured by Barrett Hodgson), Batch No. D0034', however data enclosed is of '**CARICEF** Suspension DS, Batch No. 015H of Sami Pharmaceuticals'. Please justify.	The firm have submitted that Pharmaceutical Equivalence was performed against **CARICEF** Suspension DS, Batch No. 015H of Sami Pharmaceuticals.
viii.	Furthermore, please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence.	Submitted.
ix.	2.3.P.6. It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.	Submitted.
x.	3.2.P.5.2 Analytical Procedure for FPP Testing (No. MP/R&D/FG/SOP-001-00, Effective Date 03/01/2022), Alternate Methods for Assay & Identification (By UV-Visible Spectrophotometer) have been mentioned, whereas no such methods have been recommended by USP in its monograph for 'Cefixime for Oral Suspension'. Please justify.	The firm have submitted that the Finished Proudct is tested as per USP Specifications whereas the Alternate Methods are additionally for In-process testing.
xi.	Please justify (with supporting evidence) the quantity manufactured (100 Bottles) v/s quantity required for Development / Analysis / Stability Studies etc.	The firm have submitted summary of quantity required for testing of stability batches.
xii.	Please provide certificate of 21CFR compliance of HPLC software has not been submitted.	Submitted.
xiii.	Project Name in submitted Audit Trail Reports is 'Spril Capsule'. Please justify with supporting evidence.	The firm have submitted that since the Chromatographic conditions were same, therefore, instead of creating a new file, the same folder / file was used.
xiv.	Please provide valid approval of API/ DML/GMP Certificate of API manufacturer. The enclosed copy of GMP Certificate was valid for two years from the date of inspection (22-06-2020).	The firm have submitted copy of GMP Certificate Ref. No. 204/2022-DRAP(AD-159531263130-53) dated 22-11-2022 valid for two years from the date of Inspection (18-11-2022). N/A.

xv.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	

Decision: Approved. The board decided that before issuance of registration letter, the firm shall submit Full Fee for multiple corrections / Typographical Mistake/resubmissions.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Agenda Item No. 02:

Priority Applications of Locally Manufactured Human Drugs (New DML / New Section) applied on Form - 5F.

298.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Quaper (Pvt.) Ltd. 26-A Small Industrial Estate, Lahore Road, Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper (Pvt.) Ltd. 26-A Small Industrial Estate, Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate No. 125/2022-DRAP(AD-2566507248) dated 22-08-2022 valid for three years from the date of inspection (16-08-2022) has been submitted.
	Evidence of approval of manufacturing facility	Copy of Letter for Grant of Additional Section vide No. F.1-37/2003-Lic(Vol-I) dated 29th September, 2020, mentioning Sachet (General) (New) Section has been submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26022 dated 27 OCT 2023
	Details of fee submitted	PKR 30,000/- Dated 27-10-2023 (Challan / Receipt # 55219654536)
	The proposed proprietary name / brand name	**STRONTO 2g Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Strontium Ranelate … 2g (Innovator's Specifications)
	Pharmacotherapeutic Group of (API)	M05BX03, Other drugs affecting bone structure and mineralization.
	Pharmaceutical form of applied drug	Granules for Oral Suspension
	Reference to Finished product specifications	(Innovator's Specifications)
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PROTELUS Granules for Oral Suspension, EMA Approved* *(*The marketing authorisation for Protelos has been withdrawn at the request of the marketing-authorisation holder).*
	For generic drugs (me-too status)	ONITA 2g Sachet of M/s PharmEvo Pvt. Ltd.
	Name and address of API manufacturer.	M/s Cadchem Laboratories Limited, Village Jaula Khurd, Tehsil Derabassi, Distt Ajitgarh (Mohali), Punjab, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against ONITA 2g Sachet of M/s PharmEvo Pvt. Ltd.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Cadchem Laboratories Limited, India.		
API Lot No.	SROD04210013		
Description of Pack (Container closure system)	Aluminium Foil Sachet		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	2,000 Sachets	2,000 Sachets	2,000 Sachets

Manufacturing Date	09/2022	09/2022	09/2022
Date of Initiation	09/2022	09/2022	09/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	-
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not submitted.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. CLL/EXP/21-22/23 dated 05.10.2021 for import of 100Kgs Strontium Ranelate (In-House), Batch No. SROD04210013/ SROD04210014, cleared by AD(I&E) DRAP Lahore vide No. 15293/2021 DRAP dated 12-10-2021 in the name of **M/s Bio-Mark Pharmaceuticals, Lahore** has been submitted. **No information / supporting documents regarding Loan of said API from Importer has been submitted.**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

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

Deficiencies / Shortcomings	Response of the firm
i. Please provide valid approval of API/ DML/GMP Certificate of API manufacturer issued by Regulatory Authority of Country of Origin.	Copy of GMP Certificate No. Drugs (1)Pb. 2023/4842 dated 21/6/2023 valid upto 11-08-2024 has been submitted.
ii. 3.2.P.2.2.1 In Comparative Analytical Studies, it has been mentioned that "*The Innovator Product and a Commercial Batch of '**Stronto Sachet' from the manufacturer i.e. Bio-Mark Pharmaceutical** was analysed in comparison…*". Please justify.	**Typographical error.**
iii. 3.2.P.2.2.1 Furthermore, it has been mentioned that *Target Vs Innovator/Reference Product were tested for comparative dissolution profile and results referred*. However, no such results have been enclosed within the dossier application. Please justify.	The firm have submitted that the **Dissolution Test was not performed** for finished product hence CDP was not performed.

iv.	3.2.P.5.3 Method Verification Report of Strontium Ranelate Sachet has been submitted instead of complete Analytical Method Validation, since the FPP Analytical Method is Non-pharmacopeal. Please justify.	Method Validation Report of Strontium Ranelate has been submitted.
v.	3.2.P.2.2.1 In Review of Raw Material (Batch Formula), function of Strontium Ranelate as well as Aspartame both is mentioned as Active Drugs. Please justify.	**Typographical error.**
vi.	Copy of Invoice No. CLL/EXP/21-22/23 dated 05.10.2021 for import of 100Kgs Strontium Ranelate (In-House), Batch No. SROD04210013/ SROD04210014, cleared by AD(I&E) DRAP Lahore vide No. 15293/2021 DRAP dated 12-10-2021 in the name of M/s Bio-Mark Pharmaceuticals, Lahore has been submitted. **However, no information / supporting documents regarding Loan of said API from Importer has been submitted. Please clarify / provide supporting documents.**	Copy of MoU / Letter for Loan of 5Kgs (Strontium Ranelate) from M/s Bio-Mark Pharmaceuticals, Lahore has been submitted.
vii.	Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.	Onita Sachet 2g of M/s PharmEvo Private Limited, Karachi.
viii.	Please provide 21CFR Compliance Record of HPLC software & audit trail reports on product testing.	The firm have submitted that the HPLC Software / System is not 21CFR compliant.
ix.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	N/A.

Decision: Approved. The board decided that before issuance of registration letter, the firm shall submit Full Fee for multiple corrections / Typographical Mistake/resubmissions.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

299.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Titlis Pharma (Private) Limited, 528 – A, Sundar Industrial Estate, Raiwind Road, Lahore.**
	Name, address of Manufacturing site.	M/s Titlis Pharma (Private) Limited, 528 – A, Sundar Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Copy of GMP Certificate Ref. No. 226 /2022-DRAP (AD-8386569134-1346) dated 15-12-2022 valid for two years from the date of inspection (12-12-2022) has been submitted.
	Evidence of approval of manufacturing facility	Copy of Letter for Grant of Additional Sections / Facility vide No. F.1.11/2009-Lic (Vol-I) dated 10th May 2022, mentioning **Dry Powder Sachet Section (General)** has been submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24313 dated 04 OCT 2023
	Details of fee submitted	PKR 30,000/- Dated 15-09-2023 (Challan / Receipt # 151580344771)
	The proposed proprietary name / brand name	**TITROMEP 20mg + 1680mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole … 20mg Sodium Bicarbonate … 1680mg (Innovator's Specifications)
	Pharmacotherapeutic Group of (API)	A02BC51, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton pump inhibitors.
	Pharmaceutical form of applied drug	Powder for Oral Suspension (Sachet)
	Reference to Finished product specifications	(Innovator's Specifications)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZEGERID Powder For Oral Suspension, USFDA Approved.
	For generic drugs (me-too status)	RISEK INSTA Sachet 20mg + 1680mg of M/s Getz Pharma (Pvt.) Limited.
	Name and address of API manufacturer.	**Omeprazole:** M/s Metrochem API Private Limited, Unit-IV: Plot No.: 34B, 40B & 60B, Jawaharlal Nehru Pharmacity, Thanam Village, Parawada Mandal, Visakhapatnam District-531021, Andhra Pradesh, India. **Sodium Bicarbonate:** M/s Solvay Peroxythai Limited, 1, I-3A Road, Tambol Map Ta Phut, Amphur Muang, Rayong 21150, Thailand.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical

		form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance(s) at both accelerated as well as real time conditions. **Omeprazole:** The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 Months. **Sodium Bicarbonate:** The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against RISEK INSTA Sachet 20mg + 1680mg of M/s Getz Pharma (Pvt.) Limited. Firm has submitted CDP results of their product against RISEK INSTA Sachet 20mg + 1680mg of M/s Getz Pharma (Pvt.) Limited in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Omeprazole:** M/s Metrochem API Private Limited, India. **Sodium Bicarbonate:** M/s Solvay Peroxythai Limited, Thailand.		
API Lot No.	OME-P/22096 / MTP 22921		
Description of Pack (Container closure system)	Aluminium foil sachet		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TM -02	TM -03	TM -04
Batch Size	100 Sachet	100 Sachet	100 Sachet
Manufacturing Date	DEC – 2022	DEC – 2022	DEC – 2022
Date of Initiation	30-12-2022	30-12-2022	30-12-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Dametit Tablet 5mg/850mg & 5mg/1000mg (Dapagliflozin + Metformin). Linet 2.5mg/500mg Tablets, Linet 2.5mg/850mg Tablets Linet 2.5mg/1000mg Tablets.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Omeprazole:** Copy of GMP Certificate No. L.Dis.No: E- 1862189 /DD/DCA/VSP/2022 **dated 14-11-2022, valid for 01 year from the date of issue**, has been submitted. **Sodium Bicarbonate:** Copy of Certificate of Manufacturer Ref. No. 1-2-14-03-23-00342 dated 20 JAN 2023, **Valid until December 31, 2023** has been submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Omeprazole:** Copy of Letter for Loan of 01Kgs Omeprazole Powder (Batch No. OME-P/22096) from M/s Pharmazone Chemicals Pvt. Ltd., Lahore has been submitted. **However, approval from DRAP for import of said API by M/s Pharmazone Chemicals Pvt. Ltd., Lahore has not been submitted.** **Sodium Bicarbonate:** Copy of Invoice No. L-8877 dated 15-02-2022 for Local Purchase of Sodium Bicarbonate (MTP 22921) has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

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

Deficiencies / Shortcomings	Response of the firm
i. Please provide valid GMP of API Manufacturer (Omeprazole), the enclosed GMP Certificate was valid for ONE Year from the date of issue (14-11-2022).	Copy of letter No. E-1862189/DD/DCA/VSP/2022 dated 14-11-2022 for License retention from 08-05-2022 to 07-05-2027 has been submitted.
ii. Please provide valid GMP of API Manufacturer (Sodium Bicarbonate), the enclosed Certificate was valid until December 31, 2023.	Copy of Certificate No. 1-2-07-17-24-00035 dated 14-11-2022 valid until 23 APRIL 2026 has been submitted.
iii. 2.3 Finished Product Specifications have been claimed as per Innovator's Specifications, however "Omeprazole and sodium bicarbonate for oral suspension" Monograph is available in USP. Please justify.	The firm have submitted that they were unable to find USP Monograph of Omeprazole & Sodium Bicrabonate Sachet hence they've followed Innovator's Specifications.

iv.	3.2.S.5 COA of Working Standard (of Omeprazole) has been submitted from a third party source i.e. M/s Vision Pharmaceuticals (Pvt) Ltd. Please justify.	The firm have submitted that inorder to be more stringent for testing of their product, they've used Working Standard from a third party source.
v.	3.2.P.2.2.1 Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence and CDP.	Sumitted.
vi.	Please provide approval from DRAP for import of Omeprazole Powder (Batch No. OME-P/22096) by M/s Pharmazone Chemicals Pvt. Ltd., Lahore.	Copy of AD(I&E), DRAP Lahore attested Invoice, vide No. 8669/2022 DRAP dated 25-07-2022 has been submitted.

Decision: Approved with USP Specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

300.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Titlis Pharma (Private) Limited, 528 – A, Sundar Industrial Estate, Raiwind Road, Lahore.**
	Name, address of Manufacturing site.	M/s Titlis Pharma (Private) Limited, 528 – A, Sundar Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 226 /2022-DRAP (AD-8386569134-1346) dated 15-12-2022 valid for two years from the date of inspection (12-12-2022) has been submitted.
	Evidence of approval of manufacturing facility	Copy of Letter for Grant of Additional Sections / Facility vide No. F.1.11/2009-Lic (Vol-I) dated 10th May 2022, mentioning **Dry Powder Sachet Section (General)** has been submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID: R7S-78V-YA9V Application Number: 776 dated January 10th, 2024.
	Details of fee submitted	PKR 30,000/- Dated 07-12-2023 (Challan / Receipt # 6292889503)
	The proposed proprietary name / brand name	**TITROMEP 40mg + 1680mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole … 40 mg Sodium Bicarbonate … 1680mg (Innovator's Specifications)

	Pharmacotherapeutic Group of (API)	A02BC51, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton pump inhibitors.
	Pharmaceutical form of applied drug	Powder for Oral Suspension (Sachet)
	Reference to Finished product specifications	(Innovator's Specifications)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZEGERID Powder For Oral Suspension, USFDA Approved.
	For generic drugs (me-too status)	RISEK INSTA Sachet 40mg + 1680mg of M/s Getz Pharma (Pvt.) Limited.
	Name and address of API manufacturer.	**Omeprazole:** M/s Metrochem API Private Limited, Unit-IV: Plot No.: 34B, 40B & 60B, Jawaharlal Nehru Pharmacity, Thanam Village, Parawada Mandal, Visakhapatnam District-531021, Andhra Pradesh, India. **Sodium Bicarbonate:** M/s Solvay Peroxythai Limited, 1, I-3A Road, Tambol Map Ta Phut, Amphur Muang, Rayong 21150, Thailand.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance(s) at both accelerated as well as real time conditions. **Omeprazole:** The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 Months. **Sodium Bicarbonate:** The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against RISEK INSTA Sachet 40mg + 1680mg of M/s Getz Pharma (Pvt.) Limited.

		Firm has submitted CDP results of their product against RISEK INSTA Sachet 40mg + 1680mg of M/s Getz Pharma (Pvt.) Limited in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Omeprazole:** M/s Metrochem API Private Limited, India. **Sodium Bicarbonate:** M/s Solvay Peroxythai Limited, Thailand.		
API Lot No.	OME-P/22096 / MTP 22921		
Description of Pack (Container closure system)	Aluminium foil sachet		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TM -06	TM -07	TM -08
Batch Size	250 Sachet	250 Sachet	250 Sachet
Manufacturing Date	DEC – 2022	DEC – 2022	DEC – 2022
Date of Initiation	30-12-2022	30-12-2022	30-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Dametit Tablet 5mg/850mg & 5mg/1000mg (Dapagliflozin + Metformin). Linet 2.5mg/500mg Tablets, Linet 2.5mg/850mg Tablets Linet 2.5mg/1000mg Tablets.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Omeprazole:** Copy of GMP Certificate No. L.Dis.No: E- 1862189 /DD/DCA/VSP/2022 **dated 14-11-2022, valid for 01 year from the date of issue**, has been submitted. **Sodium Bicarbonate:** Copy of Certificate of Manufacturer Ref. No. 1-2-14-03-23-00342 dated 20 JAN 2023, **Valid until December 31, 2023** has been submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Omeprazole:** Copy of Letter for Loan of 01Kgs Omeprazole Powder (Batch No. OME-P/22096) from M/s Pharmazone Chemicals Pvt. Ltd., Lahore has been submitted. **However, approval from DRAP for import of said API by M/s Pharmazone Chemicals Pvt. Ltd., Lahore has not been submitted.** **Sodium Bicarbonate:** Copy of Invoice No. L-8877 dated 15-02-2022 for Local Purchase of Sodium Bicarbonate (MTP 22921) has been submitted.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted analytical record for product testing.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

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

	Deficiencies / Shortcomings	Response of the firm
i.	Detail of Container Closure has been mentioned as *'Cardboard box with size Width X Height X Depth 65m'*. The same needs to be updated as that of Primary Container Closure.	Revised as 'Aluminum foil (three layer) used as primary packing materials'.
ii.	Please provide valid GMP of API Manufacturer (Omeprazole), the enclosed GMP Certificate was valid for ONE Year from the date of issue (14-11-2022).	Copy of letter No. E-1862189/DD/DCA/VSP/2022 dated 14-11-2022 for License retention from 08-05-2022 to 07-05-2027 has been submitted.
iii.	Please provide valid GMP of API Manufacturer (Sodium Bicarbonate), the enclosed Certificate was valid until December 31, 2023.	Copy of Certificate No. 1-2-07-17-24-00035 dated 14-11-2022 valid until 23 APRIL 2026 has been submitted.
iv.	2.3 Finished Product Specifications have been claimed as per Innovator's Specifications, however "Omeprazole and sodium bicarbonate for oral suspension" Monograph is available in USP. Please justify.	The firm have submitted that they were unable to find USP Monograph of Omeprazole & Sodium Bicrabonate Sachet hence they've followed Innovator's Specifications.
v.	3.2.S.5 COA of Working Standard (of Omeprazole) has been submitted from a third party source i.e. M/s Vision Pharmaceuticals (Pvt) Ltd. Please justify.	The firm have submitted that inorder to be more stringent for testing of their product, they've used Working Standard from a third party source.
vi.	Please provide approval from DRAP for import of Omeprazole Powder (Batch No. OME-P/22096) by M/s Pharmazone Chemicals Pvt. Ltd., Lahore.	Copy of AD(I&E), DRAP Lahore attested Invoice, vide No. 8669/2022 DRAP dated 25-07-2022 has been submitted.

Decision: Approved with USP Specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

301.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pearl Pharmaceuticals, Plot No. 204, Street No.1, I-10/3 Industrial Area, Islamabad.**

	Name, address of Manufacturing site.	M/s Pearl Pharmaceuticals, Plot No. 204, Street No.1, I-10/3 Industrial Area, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate No. F.3-101/2022-Addl. Dir. (QA&LT-1)-20 dated 28th February, 2023 valid for two years till 02-11-2024, has been submitted.
	Evidence of approval of manufacturing facility	Copy of Section Approval Letter No. F.1-18/90-Lic(Vol-III) dated 21st February, 2023 has been submitted, mentioning **Ampoule General (New) Section.**
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 18295 dated 20 JUL 2023
	Details of fee submitted	PKR 30,000/- Dated 10-07-2023 (Challan / Receipt # 33638471907)
	The proposed proprietary name / brand name	**AQUA PEARL 5ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Water for Injection … 5ml (BP Specifications)
	Pharmacotherapeutic Group of (API)	-
	Pharmaceutical form of applied drug	Clear colorless liquid filled in clear glass ampoules.
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sterile Water for Injection, USFDA Approved.
	For generic drugs (me-too status)	Water for Injection by Surge Laboratories Pvt. Ltd.
	Name and address of API manufacturer.	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to 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 studies of drug product.
	Module-III Drug Substance:	N/A Firm has submitted that the Drug Substance for Sterilized Water for Injection is Water for Injection Produced and filled on same day.
	Stability Studies of Drug Substance	N/A

	(Conditions & duration of Stability studies)	Firm has submitted that the Drug Substance for Sterilized Water for Injection is **Water for Injection Produced and filled on same day so no stability is needed.**
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Comparative Analysis Report of their Product with Water for Injection from Surge Laboratories.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug product.

STABILITY STUDY DATA

Manufacturer of API	N/A		
API Lot No.	N/A		
Description of Pack (Container closure system)	Clear glass ampoules.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	WFI - 01	WFI - 02	WFI - 03
Batch Size	1320 Ampoules	1320 Ampoules	1320 Ampoules
Manufacturing Date	03 - 2023	03 - 2023	03 - 2023
Date of Initiation	03 - 2023	03 - 2023	03 - 2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	N/A
3.	Documents for the procurement of API with approval from DRAP (in case of import).	N/A
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not submitted.**

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

Deficiencies / Shortcomings		Response of the firm
i.	Label claim has been mentioned as 'Each Ampoule Contains: Water for Injection … 5ml', whereas the same needs to be corrected as 'Each Ampoule Contains: Sterile Water for Injection … 5ml'.	The firm have submitted corrected label claim as: Each Ampoule Contains: Sterile Water for Injection … 5ml.
ii.	3.2.P.5.3 Analytical Method Verification has not been submitted in this Section.	Not submitted.
iii.	Please provide evidence (along with Batch details) for Reference / Innovator pack used for Comparative Analysis.	Submitted.
iv.	Please provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	N/A
v.	Please provide Data of 06th Month Testing supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.

Decision: Approved. The board decided that before issuance of registration letter, the firm shall submit Fee of 7500/ for corrections / Typographical Mistake/resubmissions.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

302.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pearl Pharmaceuticals, Plot No. 204, Street No.1, I-10/3 Industrial Area, Islamabad.**
	Name, address of Manufacturing site.	M/s Pearl Pharmaceuticals, Plot No. 204, Street No.1, I-10/3 Industrial Area, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate No. F.3-101/2022-Addl. Dir. (QA&LT-1)-20 dated 28th February, 2023 valid for two years till 02-11-2024, has been submitted.
	Evidence of approval of manufacturing facility	Copy of Section Approval Letter No. F.1-18/90-Lic(Vol-III) dated 21st February, 2023 has been submitted, mentioning **Ampoule General (New) Section.**
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 18294 dated 20 JUL 2023
	Details of fee submitted	PKR 30,000/- Dated 10-07-2023 (Challan / Receipt # 327582006162)
	The proposed proprietary name / brand name	**AQUA PEARL 10ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Water for Injection … 10ml (BP Specifications)
	Pharmacotherapeutic Group of (API)	-
	Pharmaceutical form of applied drug	Clear colorless liquid filled in clear glass ampoules.
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sterile Water for Injection, USFDA Approved.
	For generic drugs (me-too status)	Water for Injection by Surge Laboratories Pvt. Ltd.
	Name and address of API manufacturer.	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to 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 studies of drug product.
	Module-III Drug Substance:	N/A Firm has submitted that the Drug Substance for Sterilized Water for Injection is Water for Injection Produced and filled on same day.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	N/A Firm has submitted that the Drug Substance for Sterilized Water for Injection is **Water for Injection Produced and filled on same day so no stability is needed.**
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Comparative Analysis Report of their Product with Water for Injection from Surge Laboratories.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug product.

STABILITY STUDY DATA			
Manufacturer of API	N/A		
API Lot No.	N/A		
Description of Pack (Container closure system)	Clear glass ampoules.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	WFI - 01	WFI - 02	WFI - 03
Batch Size	857 Ampoules	857 Ampoules	857 Ampoules
Manufacturing Date	03 - 2023	03 - 2023	03 - 2023
Date of Initiation	03 - 2023	03 - 2023	03 - 2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	N/A
3.	Documents for the procurement of API with approval from DRAP (in case of import).	N/A
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

Deficiencies / Shortcomings	Response of the firm
i. Label claim has been mentioned as 'Each Ampoule Contains: Water for Injection … 5ml', whereas the same needs to be corrected as 'Each Ampoule Contains: Sterile Water for Injection … 5ml'.	The firm have submitted corrected label claim as: Each Ampoule Contains: Sterile Water for Injection … 5ml. Not submitted.

ii.	3.2.P.5.3 Analytical Method Verification has not been submitted in this Section.	Submitted.
iii.	Please provide evidence (along with Batch details) for Reference / Innovator pack used for Comparative Analysis.	N/A
iv.	Please provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted.
v.	Please provide Data of 06th Month Testing supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	

Decision: Approved. The board decided that before issuance of registration letter, the firm shall submit Rs. 7500/ for multiple corrections / Typographical Mistake/resubmissions.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Agenda of Evaluator PEC-XXIII

Case no. 01 Registration applications for local manufacturing of (Human) drugs

a. New cases (Form 5F)

303.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of report of DML renewal inspection conducted on 18-02-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 31-10-2016 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy.No 22071 dated 03-08-2022.
	Details of fee submitted	PKR 30,000/- Dated 28-07-2022
	The proposed proprietary name / brand name	**APIXANEXT 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Apixaban…2.5mg
	Pharmacotherapeutic Group of (API)	Antithrombotic agents, Direct Factor Xa inhibitors
	Pharmaceutical form of applied drug	Round biconvex film coated tablet with score line on one side
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	7's, 14's, 20's, 28's, 30's
	Proposed unit price	As per Drug Pricing Committee (DPC)/SRO
	The status in reference regulatory authorities	Eliquis Tablet 2.5mg & 5mg (USFDA Approved)
	For generic drugs (me-too status)	Eliquis Tablet 2.5mg of M/s Pfizer Pakistan Ltd, (Reg.No. 105618)
	Name and address of API manufacturer.	Changzhou Pharmaceutical Factory, No. 518 Laodong East Road, Changzhou, Jiangsu Province 213018, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of

		specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Eliquis 2.5mg Tablet marketed by Bristol Myers Squibb/Pfizer EEIG. Firm has submitted CDP results of their product against the innovator's product Eliquis 2.5mg Tablet in 3 dissolution medias. The value for similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	Changzhou Pharmaceutical Factory, No. 518 Laodong East Road, Changzhou, Jiangsu Province 213018, P.R. China.		
API Lot No.	ZSAP210402		
Description of Pack (Container closure system)	Alu-PVC Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-0010TBA	T-0011TBA	T-0012TBA
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	28-03-2022	28-03-2022	28-03-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate dated 22-10-2021 issued by Jiangsu Changzhou Drug Administration., valid till 21-10-2025.The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 17-08-2021 specifying 1Kg of Apixaban. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.6.5**	Validity of GMP certificate of drug substance manufacturer is 21-10-2021. Valid GMP certificate of drug substance manufacturer shall be submitted.	Submitted
2.	**3.2.P.8**	Results of real time and accelerated stability studies for six-month time point shall be submitted.	Submitted
3.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP shall be submitted.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitmentsubmitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

304.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of report for DML renewal based on inspection conducted on 18-02-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 31-10-2016 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22950 dated 15-08-2022.
	Details of fee submitted	PKR 30,000/- DS No. 4652230274
	The proposed proprietary name / brand name	**APIXANEXT 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Apixaban…5mg
	Pharmacotherapeutic Group of (API)	Antithrombotic agents, Direct Factor Xa inhibitors
	Pharmaceutical form of applied drug	Round biconvex film coated tablet with score line on one side
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	7's, 14's, 20's, 28's, 30's

	Proposed unit price	As per Drug Pricing Committee (DPC)/SRO
	The status in reference regulatory authorities	Eliquis Tablet 2.5mg & 5mg (USFDA Approved)
	For generic drugs (me-too status)	Eliquis Tablet 5mg of M/s Pfizer Pakistan Ltd, (Reg.No. 105619)
	Name and address of API manufacturer.	Changzhou Pharmaceutical Factory, No. 518 Laodong East Road, Changzhou, Jiangsu Province 213018, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Eliquis 5mg Tablet marketed by Bristol Myers Squibb/Pfizer EEIG. Firm has submitted CDP results of their product against the innovator's product Eliquis 5mg Tablet in 3 dissolution media. The value for similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	Changzhou Pharmaceutical Factory, No. 518 Laodong East Road, Changzhou, Jiangsu Province 213018, P.R. China.		
API Lot No.	ZSAP210402		
Description of Pack (Container closure system)	Alu-PVC Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-0003TBB	T-0004TBB	T-0005TBB
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	26-04-2022	26-04-2022	26-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate dated 22-10-2021 issued by Jiangsu Changzhou Drug Administration., valid till 21-10-2025.The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 17-08-2021 specifying 1Kg of Apixaban. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
4.	**1.6.5**	Validity of GMP certificate of drug substance manufacturer is 21-10-2021. Valid GMP certificate of drug substance manufacturer shall be submitted.	Submitted
5.	**3.2.P.8**	Results of real time and accelerated stability studies for six-month time point shall be submitted.	Submitted
6.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP shall be submitted.	Submitted

Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitmentsubmitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
305.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of report for DML renewal based on inspection conducted on 18-02-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 31-10-2016 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 25240 dated 06-09-2022.
	Details of fee submitted	PKR 30,000/- DS No. 27600161
	The proposed proprietary name / brand name	**ERTUNEXT 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid…6.48mg eq. to 5mg of Ertugliflozin
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding insulins, sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Pharmaceutical form of applied drug	Round biconvex film coated tablet plain from both sides
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	7's, 14's, 20's, 28's, 30's
	Proposed unit price	As per Drug Pricing Committee (DPC)/SRO
	The status in reference regulatory authorities	Steglatro Tablet 5mg (USFDA Approved)
	For generic drugs (me-too status)	Ertuget Tablet 5mg of M/s Getz Pharma Pvt Ltd, (Reg.No. 110368)
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu, Fuxin City, Liaoning Province 123000, P.R. China.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Steglatro 5mg Tablet by MSD Sub Merck. Firm has submitted CDP results of their product against the innovator's product Steglatro 5mg Tablet in 3 dissolution medias. The value for similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.
STABILITY STUDY DATA		
Manufacturer of API	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu, Fuxin City, Liaoning Province 123000, P.R. China.	

API Lot No.	L-IG-20211005-D01-IG06-03		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-0002TBC	T-0003TBC	T-0004TBC
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	03-2022	04-2022	04-2022
Date of Initiation	10-05-2022	10-05-2022	10-05-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License No. 20150233 valid till 17-11-2027
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.6.5**	Validity of GMP certificate of drug substance manufacturer is 23-08-2023. Valid GMP certificate of drug substance manufacturer issued by the relevant regulatory authority of the country of origin shall be submitted.	Firm has submitted copy of API manufacturer's License No. 20150233 valid till 17-11-2027 issued by Liaoning Provincial Food and Drug Administration
2.	**2.3.S.4 & 3.2.S.4**	Specifications of drug substance shall include content limit for LPGA and Ertugliflozin LPGA.	Revised specifications, analytical method and CoA are submitted.
3.	**3.2.S.7**	Long term stability studies of the Drug substance shall be submitted as per Zone-IVa conditions.	Submitted.
4.	**3.2.P.5**	Specifications do not include content of Ertugliflozin LPGA and LPGA. Justify.	Applicant has submitted revised specifications.
5.	**3.2.P.8**	Results of real time and accelerated stability studies for six-month time point shall be submitted.	Submitted.

	6.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP shall be submitted.	*ADC attested invoice / clearance certificate is not submitted.*

Decision: Approved. Applicant shall submit commercial invoice attested by AD I&E DRAP or clearance certificate issued by AD I&E DRAP for procurement of API, before issuance of registration letter. The board further decided that before issuance of registration letter, the firm shall submit Fee Rs. 7500/ for resubmissions

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitmentsubmitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

306.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Daghal, Rawalpindi.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Daghal, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted on 16-02-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of DML renewal wef 07-01-2016 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 23834 dated 23-08-2022.
	Details of fee submitted	PKR 30,000/- DS No. 3539369309
	The proposed proprietary name / brand name	**APLO 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Apixaban…2.5mg
	Pharmacotherapeutic Group of (API)	Antithrombotic agents, Direct Factor Xa inhibitors
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	10's, 14's
	Proposed unit price	As per Drug Pricing Committee (DPC)/SRO
	The status in reference regulatory authorities	Eliquis Tablet 2.5mg & 5mg (USFDA Approved)
	For generic drugs (me-too status)	Eliquis Tablet 2.5mg of M/s Pfizer Pakistan Ltd, (Reg.No. 105618)
	Name and address of API manufacturer.	Glenmark Life Sciences Ltd, Plot 3109, GIDC, Industrial Estate, Ankleshwar, District Bharuch.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product Apiban 2.5mg Tablet by M/s Highnoon. Firm has submitted CDP results of their product against the innovator's product Apiban 2.5mg Tablet by M/s Highnoon in 3 dissolution medias. The value for similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA	
Manufacturer of API	Glenmark Life Sciences Ltd, Plot 3109, GIDC, Industrial Estate, Ankleshwar, District Bharuch.
API Lot No.	802008793
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	20-10-2021	24-10-2021	24-10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. 19061427 dated 18-06-2019 issued by Food and Drugs Control Administration. The certificate specifies that the firm is operating at satisfactory level of GMP compliance. The certificate is valid till 17-06-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 16-09-2021 specifying 0.2Kg of Apixaban. The invoice is cleared by AD (I&E) DRAP, Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr.No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.3.4**	DML of drug product manufacturer was valid till 06-01-2021. Copy of valid DML issued by DRAP shall be submitted.	Copy of valid DML No. 000333 renewed w.e.f. 07-01-2021 is submitted.
2.	**1.6.5**	Valid DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted as the submitted DML was valid till 31-12-2023.	Copy of GMP certificate valid till 05/06/2025 is submitted.
3.	**3.2.S.4.1**	Specifications of drug substance in 3.2.S.4.1 are different from those given in CoA of drug substance in 3.2.S.4.4. Justify.	Revised specifications submitted.
4.	**3.2.S.4.4**	CoA of drug substance generated by drug product manufacturer for Batch Number 802008793 (Mfg 11-20, Expiry 12-24) shall be submitted.	Submitted.
5.	**3.2.S.7**	Long term stability studies of drug substance conducted at Zone IV-a conditions throughout the claimed shelf life shall be submitted.	Submitted.

	6.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP shall be submitted.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitmentsubmitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

307.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Daghal, Rawalpindi.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Daghal, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted on 16-02-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of DML renewal wef 07-01-2016 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 22727 dated 11-08-2022.
	Details of fee submitted	PKR 30,000/- DS No. 23409526937
	The proposed proprietary name / brand name	**APLO 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Apixaban…5mg
	Pharmacotherapeutic Group of (API)	Antithrombotic agents, Direct Factor Xa inhibitors
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	10's, 14's
	Proposed unit price	As per Drug Pricing Committee (DPC)/SRO
	The status in reference regulatory authorities	Eliquis Tablet 2.5mg & 5mg (USFDA Approved)
	For generic drugs (me-too status)	Apiban Tablet 5mg of M/s Highnoon (Reg.No. 104682)
	Name and address of API manufacturer.	Glenmark Life Sciences Ltd, Plot 3109, GIDC, Industrial Estate, Ankleshwar, District Bharuch.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product Apiban 5mg Tablet by M/s Highnoon. Firm has submitted CDP results of their product against the innovator's product Apiban 5mg Tablet by M/s Highnoon in 3 dissolution medias. The value for similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	Glenmark Life Sciences Ltd, Plot 3109, GIDC, Industrial Estate, Ankleshwar, District Bharuch.
API Lot No.	802008793
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	26-10-2021	26-10-2021	26-10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. 19061427 dated 18-06-2019 issued by Food and Drugs Control Administration. The certificate specifies that the firm is operating at satisfactory level of GMP compliance. The certificate is valid till 17-06-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 16-09-2021 specifying 0.2Kg of Apixaban. The invoice is cleared by AD (I&E) DRAP, Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr.No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.3.4**	DML of drug product manufacturer was valid till 06-01-2021. Copy of valid DML issued by DRAP shall be submitted.	Copy of valid DML No. 000333 renewed w.e.f. 07-01-2021 is submitted.
2.	**1.6.5**	Valid DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted as the submitted DML was valid till 31-12-2023.	Copy of GMP certificate valid till 05/06/2025 is submitted.
3.	**3.2.S.4.1**	Specifications of drug substance in 3.2.S.4.1 are different from those given in CoA of drug substance in 3.2.S.4.4. Justify.	Revised specifications submitted.
4.	**3.2.S.4.4**	CoA of drug substance generated by drug product manufacturer for Batch Number 802008793 (Mfg 11-20, Expiry 12-24) shall be submitted.	Submitted.
5.	**3.2.S.7**	Long term stability studies of drug substance conducted at Zone IV-a conditions throughout the claimed shelf life shall be submitted.	Submitted.

6.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP shall be submitted.	Submitted.

Decision: Approved. The board decided that before issuance of registration letter, the firm shall submit Fee of Rs. 7500/ for resubmissions

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitmentsubmitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

308.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Firm has submitted copy of GMP certificate dated 20-06-2022 based on inspection conducted on 13-06-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML No. 000667 renewed w.e.f. from 10-06-2019 and approval letter for the following four sections: Tablet (General), Capsule (General), Dry Powder for Sachet (General) & Oral Liquid (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26565 dated: 20-09-2022
	Details of fee submitted	PKR 30,000/- DS No. 7608363281
	The proposed proprietary name / brand name	**NOSTIF-K 50mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Diclofenac Potassium…50mg
	Pharmacotherapeutic Group of (API)	M01AB05, Anti-inflammatory and Antirheumatic Products, Non-Steroids Acetic acid derivatives and related substances.
	Pharmaceutical form of applied drug	Powder for Oral Solution (Sachet).
	Reference to Finished product specifications	USP specification
	Proposed Pack size	10’s, 20’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cambia Powder for Oral Solution by Assertio (USFDA approved).
	For generic drugs (me-too status)	Diclovis-K 50mg Sachet by Vision Pharmaceuticals. (Reg.No. 109783).
	Name and address of API manufacturer.	M/s Henan Dongtai Pharm Co., Ltd.

		No.2, East Kangtai Road, Tangyin County, Anyang City, Henan Province, P. R. China. 456150.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturer, specifications, analytical procedures and their verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at accelerated and real time conditions of Zone IV-A. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard, container closure system and stability studies.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product i.e. Catafast Oral Powder for Solution 50mg by M/s Novartis Pharma AG Basle, Switzerland. Firm has submitted CDP results of their product against the comparator product i.e. Catafast Oral Powder for Solution 50mg by M/s Novartis Pharma AG Basle, Switzerland in three dissolution media (i.e. pH 1.2, pH 4.5, pH 6.8. The value for similarity factor is in the acceptable range
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Henan Dongtai Pharm Co., Ltd. No.2, East Kangtai Road, Tangyin County, Anyang City, Henan Province, P. R. China. 456150.
API Lot No.	B#: 303210413-5
Description of Pack	Alu-foil sachet

(Container closure system)			
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-003	T-004	T-005
Batch Size	1000 sachets.	1000 sachets.	1000 sachets.
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	21-04-2022	21-04-2022	21-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. HA20190077) dated 06-11-2021 issued by China Food and Drugs Administration. The certificate specifies that the firm complies with Chinese GMP for pharmaceutical products. The certificate is valid till 05-11-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice for import of 600kg Diclofenac Potassium cleared by AD (I&E) DRAP, Lahore on 06-09-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Serial No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**3.2.P.8**	Results/ supporting data of real time and accelerated stability studies for six-month time point shall be submitted.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitmentsubmitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

309.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals

		3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Firm has submitted copy of GMP certificate dated 20-06-2022 based on inspection conducted on 13-06-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML No. 000667 renewed w.e.f. from 10-06-2019 and approval letter for the following four sections: Tablet (General), Capsule (General), Dry Powder for Sachet (General) & Oral Liquid (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26863 dated: 22-09-2022
	Details of fee submitted	PKR 30,000/- DS No. 971040268526
	The proposed proprietary name / brand name	**EMPAGLIF 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…10mg
	Pharmacotherapeutic Group of (API)	A10BK03, Blood Glucose Lowering Drugs, Excl. Insulins
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	10's, 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Jardiance 10mg Tablet by Boehringer Ingelheim (USFDA approved).
	For generic drugs (me-too status)	Diampa 10mg Tablet by Getz Pharmaceuticals. (Reg.No. 93073).
	Name and address of API manufacturer.	M/s Jiangsu Yongan Pharmaceuticals Co. Ltd. Address: No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data

		related to nomenclature, structure, general properties, solubility, physical form, manufacturer, specifications, analytical procedures and their verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at accelerated and real time conditions of Zone IV-A. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 12 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard, container closure system and stability studies.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product i.e. Diampa 10mg Tablet by M/s Getz Pharmaceuticals. Firm has submitted CDP results of their product against the comparator product i.e. Diampa 10mg Tablet by M/s Getz Pharmaceuticals in three dissolution media (i.e. pH 1.2, pH 4.5, pH 6.8. The value for similarity factor is in the acceptable range
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance and analytical method validation study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Jiangsu Yongan Pharmaceuticals Co. Ltd. No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China.		
API Lot No.	4500-202111001		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	2000 tablets.	2000 tablets.	2000 tablets.
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	23-05-2022	23-05-2022	23-05-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. JS2020921) dated 21-09-2020 issued by Jiangsu Drug Administration. The certificate specifies that the firm complies with Chinese GMP for pharmaceutical products. The certificate is valid till 20-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice for import of 2kgs Empagliflozin cleared by AD (I&E) DRAP, Lahore dated 07-12-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Serial No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**3.2.P.8**	Results/ supporting data of real time and accelerated stability studies for six-month time point shall be submitted.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitmentsubmitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

310.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Firm has submitted copy of GMP certificate dated 20-06-2022 based on inspection conducted on 13-06-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML No. 000667 renewed w.e.f. from 10-06-2019 and approval letter for the following four sections: Tablet (General), Capsule (General), Dry Powder for Sachet (General) & Oral Liquid (General).
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26864 dated: 22-09-2022
	Details of fee submitted	PKR 30,000/- DS No. 03257486570
	The proposed proprietary name / brand name	**EMPAGLIF 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…25mg
	Pharmacotherapeutic Group of (API)	A10BK03, Blood Glucose Lowering Drugs, Excl. Insulins
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	10's, 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Jardiance 25mg Tablet by Boehringer Ingelheim (USFDA approved).
	For generic drugs (me-too status)	Diampa 25mg Tablet by Getz Pharmaceuticals. (Reg.No. 93074).
	Name and address of API manufacturer.	M/s Jiangsu Yongan Pharmaceuticals Co. Ltd. Address: No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturer, specifications, analytical procedures and their verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at accelerated and real time conditions of Zone IV-A. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 12 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process

		and control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard, container closure system and stability studies.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product i.e. Diampa 25mg Tablet by M/s Getz Pharmaceuticals. Firm has submitted CDP results of their product against the comparator product i.e. Diampa 25mg Tablet by M/s Getz Pharmaceuticals in three dissolution media (i.e. pH 1.2, pH 4.5, pH 6.8. The value for similarity factor is in the acceptable range
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance and analytical method validation study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangsu Yongan Pharmaceuticals Co. Ltd. No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China.		
API Lot No.	4500-202111001		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-003	T-004	T-005
Batch Size	1500 tablets.	1500 tablets.	1500 tablets.
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	09-05-2022	09-05-2022	09-05-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. JS2020921) dated 21-09-2020 issued by Jiangsu Drug Administration. The certificate specifies that the firm complies with Chinese GMP for pharmaceutical products. The certificate is valid till 20-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice for import of 2kgs Empagliflozin cleared by AD (I&E) DRAP, Lahore dated 07-12-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Serial No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**3.2.P.8**	Results/ supporting data of real time and accelerated stability studies for six-month time point shall be submitted.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitmentsubmitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

311.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High-Q Pharmaceuticals Plot No.224 & 225/1, Sector 23, Korangi Industrial Area, Karachi-Pakistan.**
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals Plot No.224 & 225/1, Sector 23, Korangi Industrial Area, Karachi-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 58/2021-DRAP (K) dated 21-12-2021 issued on the basis of evaluation conducted on 30-06-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant/renewal of section dated 17-09-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 26865 dated 22-09-2022.
	Details of fee submitted	PKR 30,000/- DS No. 41112290904
	The proposed proprietary name / brand name	**APIXA 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Apixaban…2.5mg
	Pharmacotherapeutic Group of (API)	Antithrombotic agents, Direct Factor Xa inhibitors
	Pharmaceutical form of applied drug	Round film coated tablets with both sides plain
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	10's, 14's, 28's, 30's

	Proposed unit price	As per Drug Pricing Committee (DPC)/SRO
	The status in reference regulatory authorities	Eliquis Tablet 2.5mg & 5mg (USFDA Approved)
	For generic drugs (me-too status)	Eliquis Tablet 2.5mg of M/s Pfizer Pakistan Ltd, (Reg.No. 105618) & Apixaget Tablet 2.5mg of M/s Getz Pharma (Pvt) Ltd (Reg.No. 105247)
	Name and address of API manufacturer.	Jiangsu Yongan Pharmaceutical Co., Limited. No.18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Apixaget Tablet 2.5mg of M/s Getz Pharma (Pvt) Ltd. Firm has submitted CDP results of their product against the innovator's product Apixaget Tablet 2.5mg of M/s Getz Pharma (Pvt) Ltd in 3 dissolution medias. The value for similarity factor is in the acceptable range.

	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	Jiangsu Yongan Pharmaceutical Co., Limited. No.18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China.		
API Lot No.	APB-201909001		
Description of Pack (Container closure system)	Alu-PVC Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	2APPD01/21	2APPD02/21	2APPD03/21
Batch Size	9523 Tablet	9523 Tablet	9523 Tablet
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	30-06-2021	30-06-2021	30-06-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Vesoft Tablet, for which the inspection was conducted on 12-07-2018 and the report was presented in 284th meeting of Registration Board. The report confirms following points: vii. The HPLC software is 21CFR compliant. viii. Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML No. Su20160324 dated 07-12-2020 issued by Jiangsu Medical Products Administration. The certificate is valid till 06-12-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 28-10-2019 specifying import of 2.5Kg of Apixaban. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant

1.	**3.2.S.4**	The Expiry date of drug substance given on invoice is 08-21 whereas on CoA the expiry is 05-2022. Clarification shall be submitted.	Typographical error. Revised CoA submitted
2.	**3.2.S.7**	Long term stability studies data is submitted for 18 months. Stability studies data shall be submitted for complete shelf life of the drug substance.	Submitted

Decision: Approved. The board decided that before issuance of registration letter, the firm shall submit Fee of Rs. 7500/ for resubmissions

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitmentsubmitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

312.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High-Q Pharmaceuticals Plot No.224 & 225/1, Sector 23, Korangi Industrial Area, Karachi-Pakistan.**
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals Plot No.224 & 225/1, Sector 23, Korangi Industrial Area, Karachi-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 58/2021-DRAP (K) dated 21-12-2021 issued on the basis of evaluation conducted on 30-06-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant/renewal of section dated 17-09-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 26866 dated 22-09-2022.
	Details of fee submitted	PKR 30,000/- DS No. 09119004455
	The proposed proprietary name / brand name	**APIXA 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Apixaban…5mg
	Pharmacotherapeutic Group of (API)	Antithrombotic agents, Direct Factor Xa inhibitors
	Pharmaceutical form of applied drug	Round film coated tablets with both sides plain
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	10's, 14's, 28's, 30's
	Proposed unit price	As per Drug Pricing Committee (DPC)/SRO
	The status in reference regulatory authorities	Eliquis Tablet 2.5mg & 5mg (USFDA Approved)
	For generic drugs (me-too status)	Apixaget Tablet 5mg of M/s Getz Pharma (Pvt) Ltd (Reg.No. 105248)

	Name and address of API manufacturer.	Jiangsu Yongan Pharmaceutical Co., Limited. No.18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Apixaget Tablet 5mg of M/s Getz Pharma (Pvt) Ltd. Firm has submitted CDP results of their product against the innovator's product Apixaget Tablet 5mg of M/s Getz Pharma (Pvt) Ltd in 3 dissolution medias. The value for similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA	
Manufacturer of API	Jiangsu Yongan Pharmaceutical Co., Limited. No.18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China.
API Lot No.	APB-201909001
Description of Pack (Container closure system)	Alu-PVC Blister

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	5APPD01/21	5APPD02/21	5APPD03/21
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	05-2021	05-2021	06-2021
Date of Initiation	30-06-2021	30-06-2021	30-06-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Vesoft Tablet, for which the inspection was conducted on 12-07-2018 and the report was presented in 284th meeting of Registration Board. The report confirms following points: i. The HPLC software is 21CFR compliant. ii. Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML No. Su20160324 dated 07-12-2020 issued by Jiangsu Medical Products Administration. The certificate is valid till 06-12-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 28-10-2019 specifying import of 2.5Kg of Apixaban. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**3.2.S.4**	The Expiry date of drug substance given on invoice is 08-21 whereas on CoA the expiry is 05-2022. Clarification shall be submitted.	Typographical error. Revised CoA submitted
2.	**3.2.S.7**	Long term stability studies data is submitted for 18 months. Stability studies data shall be submitted for complete shelf life of the drug substance.	Submitted

Decision: Approved. The board decided that before issuance of registration letter, the firm shall submit Fee of Rs. 7500/ for resubmissions

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitmentsubmitted in**

the registration application.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case no. 02 Registration applications of newly granted DML or New section (Human)

a. New /Additional section(s)

CLB in its 286th meeting held on 11th May, 2022 has considered and approved the renewal of DML by way of Formulation with following section: • Dry Powder Injection (Cephalosporin)-New		
313.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals Pvt. Limited, Plot No. 129, Sunder Industrial Estate Lahore.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals Pvt. Limited, Plot No. 129, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 08-09-2021 based on inspection conducted on 08-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML/grant of section dated 07-06-2022 specifying grant of Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13386 dated 30-05-2023
	Details of fee submitted	PKR 30,000/- Deposit Slip No. 53123321760
	The proposed proprietary name / brand name	**Cefurox 250mg IV/IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefuroxime Sodium Equivalent to Cefuroxime…250mg
	Pharmacotherapeutic Group of (API)	Cephalosporins
	Pharmaceutical form of applied drug	Powder for injection
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Zinacef Injection 250mg of M/s GlaxoSmithKline Pakistan Limited (Reg. No. 6221)
	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd. Address: Economic & Technological Development Zone, First Medical Zone, Datong Shanxi, China.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, manufacturing process and process control, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has also summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, manufacturing process and process control, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	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 drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator's product Zinacef Injection. CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study report for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd. Economic & Technological Development Zone, First Medical Zone, Datong Shanxi, China.
API Lot No.	F012104006 Manufacturing date 04-2021, Expiry 03-2024
Description of Pack (Container closure system)	10mL Type 2 USP glass vial packed in unit carton provided with leaflet and reconstitution diluent (WFI).
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TCD001	TCD002	TCD003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	18-07-2022	19-07-2022	20-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. SX20180229 dated 06-06-2018 issued by Shanxi Province Food and Drug Administration, China. The certificate specifies that the firm is operating at satisfactory level of GMP compliance. GMP certificate validity: 05/06/2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted loan letter from M/s Medisave Pharmaceuticals, Lahore dated 02-07-2022 specifying 5Kg loan of Cefuroxime Sodium sterile. Firm has also submitted copy of commercial invoice cleared on 22-11-2021 specifying import of 30kg of Cefuroxime Sodium sterile USP. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

314.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals Pvt. Limited, Plot No. 129, Sunder Industrial Estate Lahore.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals Pvt. Limited, Plot No. 129, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 08-09-2021 based on inspection conducted on 08-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML/grant of section dated 07-06-2022 specifying grant of Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13387 dated 30-05-2023
	Details of fee submitted	PKR 30,000/- Deposit Slip No. 40856319233
	The proposed proprietary name / brand name	**Cefurox 750mg IV/IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefuroxime Sodium Equivalent to Cefuroxime…750mg
	Pharmacotherapeutic Group of (API)	Cephalosporins
	Pharmaceutical form of applied drug	Powder for injection
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Zinacef Injection 750mg of M/s GlaxoSmithKline Pakistan Limited (Reg. No. 6222)
	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd. Address: Economic & Technological Development Zone, First Medical Zone, Datong Shanxi, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, manufacturing process and process control, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has also summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, manufacturing process and process control, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ±

		5% RH for 36 months.
	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 drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator's product Zinacef Injection. CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study report for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd. Economic & Technological Development Zone, First Medical Zone, Datong Shanxi, China.		
API Lot No.	F012104006 Manufacturing date 04-2021, Expiry 03-2024		
Description of Pack (Container closure system)	10mL Type 2 USP glass vial packed in unit carton provided with leaflet and reconstitution diluent (WFI).		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TCG001	TCG002	TCG003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	21-07-2022	22-07-2022	23-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. SX20180229 dated 06-06-2018 issued by Shanxi Province Food and Drug Administration, China. The certificate specifies that the firm is operating at satisfactory level of GMP compliance. GMP certificate validity: 05/06/2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted loan letter from M/s Medisave Pharmaceuticals, Lahore dated 02-07-2022 specifying 5Kg loan of Cefuroxime Sodium sterile. Firm has also submitted copy of commercial invoice cleared on 22-11-2021 specifying import of 30kg of Cefuroxime Sodium sterile USP. The invoice is cleared by AD (I&E) DRAP, Lahore.

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

315.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals Pvt. Limited, Plot No. 129, Sunder Industrial Estate Lahore.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals Pvt. Limited, Plot No. 129, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 08-09-2021 based on inspection conducted on 08-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML/grant of section dated 07-06-2022 specifying grant of Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13388 dated 30-05-2023
	Details of fee submitted	PKR 30,000/- Deposit Slip No. 1022165116
	The proposed proprietary name / brand name	**Cefurox 1.5g IV/IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefuroxime Sodium Equivalent to Cefuroxime…1.5g
	Pharmacotherapeutic Group of (API)	Cephalosporins
	Pharmaceutical form of applied drug	Powder for injection
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Zinacef Injection 1.5g of M/s GlaxoSmithKline Pakistan Limited (Reg. No. 22104)
	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd. Address: Economic & Technological Development Zone, First Medical Zone, Datong Shanxi, China.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, manufacturing process and process control, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has also summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, manufacturing process and process control, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	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 drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator's product Zinacef Injection. CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study report for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd. Economic & Technological Development Zone, First Medical Zone, Datong Shanxi, China.
API Lot No.	F012104006 Manufacturing date 04-2021, Expiry 03-2024
Description of Pack (Container closure system)	Type 2 USP glass vial packed in unit carton provided with leaflet and reconstitution diluent (WFI).
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TCJ001	TCJ002	TCJ003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	24-07-2022	25-07-2022	26-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. SX20180229 dated 06-06-2018 issued by Shanxi Province Food and Drug Administration, China. The certificate specifies that the firm is operating at satisfactory level of GMP compliance. GMP certificate validity: 05/06/2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted loan letter from M/s Medisave Pharmaceuticals, Lahore dated 02-07-2022 specifying 5Kg loan of Cefuroxime Sodium sterile. Firm has also submitted copy of commercial invoice cleared on 22-11-2021 specifying import of 30kg of Cefuroxime Sodium sterile USP. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Section	Observations/shortcomings/deficiencies	Reply of applicant
1.		DML of M/s Wimits has been renewed w.e.f 03-02-2019. Receiving of application for DML renewal from 2024 onwards submitted in Licensing Division, DRAP shall be submitted.	Application for DML renewal submitted in Licensing Division of DRAP dated 01-02-2024 is provided.
2.	**1.6.5**	Valid GMP certificate of the drug substance manufacturer issued by the relevant regulatory authority of the country of origin shall be submitted.	Valid DML of API manufacturer (20160008) is submitted.
3.	**3.2.S.6 & 3.2.S.7**	Label of drug substance states the storage conditions as 2-8˚C. Stability studies of the drug substance are conducted at following condition: Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	On the submitted CoA of API, there is no reference of special storage conditions. Hence the storage conditions of the API are below 30˚C.

			However, the stability studies report concludes that the "shelf life of Cefuroxime sodium is three years if the product is preserved….at 2-8˚C". Clarify the storage conditions of the drug substance and submit stability studies data accordingly.	Stability studies have been submitted accordingly as per Zone Iva conditions.
	4.	**3.2.P.2.2.1**	• Details of innovator / reference/ comparator product including name and address of manufacturer and marketing authorization holder shall be submitted. • Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference/ comparator product and ***results of all the quality tests*** (mentioned in USP or section 3.2.P.5.1 of instant application) of the developed formulation and the innovator / reference /comparator product shall be submitted and discussed.	• Reference product details: Zinacef Injection IM/IV Manufcaturer: M/s GSK Pakistan Ltd, Plot No. 5, Sector 21, Korangi Industrial Area, Karachi. • Complete pharmaceutical equivalence report submitted.
	5.	**3.2.P.2.6**	Reference product manufacturer recommends that "From a microbiological point of view once opened, the product should be used immediately. If not used immediately in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C when prepared in water for injections". Applicant has conducted satisfactory in-use stability studies with sterile WFI at 30˚C ± 2˚C / 65% ± 5%RH. Justification shall be submitted regarding the in-use stability storage conditions.	Conditions for in-use stability were 2-8°C for 24 hours whereas it was inadvertently written as 30˚C ± 2˚C / 65% ± 5%RH.

Decision: Registration Board approved the applications of Cefurox 250mg IV/IM Injection, Cefurox 750mg IV/IM Injection & Cefurox 1.5g IV/IM Injection.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitmentsubmitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

316.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals Pvt. Limited, Plot No. 129, Sunder Industrial Estate Lahore.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals Pvt. Limited, Plot No. 129, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 08-09-2021 based on inspection conducted on 08-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML/grant of section dated 07-06-2022 specifying grant of Dry Powder Injection (Cephalosporin) section wef 03-02-2019.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13382 dated 30-05-2023
	Details of fee submitted	PKR 30,000/- Deposit Slip No. 6298158569
	The proposed proprietary name / brand name	**Ceframit 250mg IV/IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cephradine …….250mg (with L-Arginine)
	Pharmacotherapeutic Group of (API)	Cephalosporins
	Pharmaceutical form of applied drug	Powder for solution for injection
	Reference to Finished product specifications	In-house Specifications
	Proposed Pack size	1 x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Velosef Injection of M/s GlaxoSmithKline Pakistan Limited (Reg. No. 1870)
	Name and address of API manufacturer.	M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. Address: 98 Hainan Road, Economic Technology Development Zone, Shijiazhuang, Hebei, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, manufacturing process and process control, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has also summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, manufacturing process and process control, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ±

		5% RH for 36 months.
	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 drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator's product Velosef Injection. CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study report for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. Address: 98 Hainan Road, Economic Technology Development Zone, Shijiazhuang, Hebei, China.		
API Lot No.	B2172108010 Manufacturing date 08-2021, Expiry 07-2023		
Description of Pack (Container closure system)	Glass vial packed in unit carton provided with leaflet and reconstitution diluent (WFI).		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TJA001	TJA002	TJA003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	26-08-2022	27-08-2022	28-08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. HE20180086 dated 15-10-2018 issued by Hebei Food and Drug Administration, PRC. The certificate specifies that the firm is operating at satisfactory level of GMP compliance. GMP certificate validity: 14/10/2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted loan letter from M/s Novamed Pharmaceuticals, Lahore dated 10-08-2022 specifying 5Kg loan of Cephradine with L-Arginine sterile. Firm has also submitted copy of commercial invoice cleared on 02-12-2021 specifying import of 104kg of Cephradine with L-Arginine sterile. The invoice is cleared by AD (I&E) DRAP, Lahore.

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

317.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals Pvt. Limited, Plot No. 129, Sunder Industrial Estate Lahore.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals Pvt. Limited, Plot No. 129, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 08-09-2021 based on inspection conducted on 08-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML/grant of section dated 07-06-2022 specifying grant of Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13383 dated 30-05-2023
	Details of fee submitted	PKR 30,000/- Dated 17-05-2023
	The proposed proprietary name / brand name	**Ceframit 500mg IV/IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cephradine …….500mg (with L-Arginine)
	Pharmacotherapeutic Group of (API)	Cephalosporins
	Pharmaceutical form of applied drug	Powder for solution for injection
	Reference to Finished product specifications	In-house Specifications
	Proposed Pack size	1 x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Velosef Injection of M/s GlaxoSmithKline Pakistan Limited (Reg. No. 1866)
	Name and address of API manufacturer.	M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. Address: 98 Hainan Road, Economic Technology Development Zone, Shijiazhuang, Hebei, China.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, manufacturing process and process control, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has also summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, manufacturing process and process control, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	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 drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator's product Velosef Injection. CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study report for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. Address: 98 Hainan Road, Economic Technology Development Zone, Shijiazhuang, Hebei, China.
API Lot No.	B2172108010 Manufacturing date 08-2021, Expiry 07-2023
Description of Pack (Container closure system)	Glass vial packed in unit carton provided with leaflet and reconstitution diluent (WFI).
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TJB001	TJB002	TJB003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	29-08-2022	30-08-2022	31-08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. HE20180086 dated 15-10-2018 issued by Hebei Food and Drug Administration, PRC. The certificate specifies that the firm is operating at satisfactory level of GMP compliance. GMP certificate validity: 14/10/2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted loan letter from M/s Novamed Pharmaceuticals, Lahore dated 10-08-2022 specifying 5Kg loan of Cephradine with L-Arginine sterile. Firm has also submitted copy of commercial invoice cleared on 02-12-2021 specifying import of 104kg of Cephradine with L-Arginine sterile. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

318.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals Pvt. Limited, Plot No. 129, Sunder Industrial Estate Lahore.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals Pvt. Limited, Plot No. 129, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 08-09-2021 based on inspection conducted on 08-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML/grant of section dated 07-06-2022 specifying grant of Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13482 dated 30-05-2023
	Details of fee submitted	PKR 30,000/- Dated 17-05-2023
	The proposed proprietary name / brand name	**Ceframit 1g IV/IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cephradine …….1g (with L-Arginine)
	Pharmacotherapeutic Group of (API)	Cephalosporins
	Pharmaceutical form of applied drug	Powder for solution for injection
	Reference to Finished product specifications	In-house Specifications
	Proposed Pack size	1 x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Velosef Injection of M/s GlaxoSmithKline Pakistan Limited (Reg. No. 001869)
	Name and address of API manufacturer.	M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. Address: 98 Hainan Road, Economic Technology Development Zone, Shijiazhuang, Hebei, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, manufacturing process and process control, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has also summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, manufacturing process and process control, specifications, analytical procedures and verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ±

		5% RH for 36 months.
	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 drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator's product Velosef Injection. CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study report for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. Address: 98 Hainan Road, Economic Technology Development Zone, Shijiazhuang, Hebei, China.		
API Lot No.	B2172108010 Manufacturing date 08-2021, Expiry 07-2023		
Description of Pack (Container closure system)	Glass vial packed in unit carton provided with leaflet and reconstitution diluent (WFI).		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TJC001	TJC002	TJC003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	01-09-2022	02-09-2022	03-09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. HE20180086 dated 15-10-2018 issued by Hebei Food and Drug Administration, PRC. The certificate specifies that the firm is operating at satisfactory level of GMP compliance. GMP certificate validity: 14/10/2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted loan letter from M/s Novamed Pharmaceuticals, Lahore dated 10-08-2022 specifying 5Kg loan of Cephradine with L-Arginine sterile. Firm has also submitted copy of commercial invoice cleared on 02-12-2021 specifying import of 104kg of Cephradine with L-Arginine sterile. The invoice is cleared by AD (I&E) DRAP, Lahore.

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

Remarks of Evaluator[xxiii]:

Sr. No.	Section	Observations/shortcomings/deficiencies	Reply of applicant
1.		DML of M/s Wimits has been renewed w.e.f 03-02-2019. Receiving of application for DML renewal from 2024 onwards submitted in Licensing Division, DRAP shall be submitted.	Application for DML renewal submitted in Licensing Division of DRAP dated 01-02-2024 is provided.
2.	**1.6.5**	Valid GMP certificate of the drug substance manufacturer issued by the relevant regulatory authority of the country of origin shall be submitted.	Submitted.
3.	**3.2.S.4.5, 3.2.S.7, 3.2.P.8**	CoA of drug substance states the storage conditions as not exceeding 10°C. Stability studies of the drug substance are conducted at following condition: Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH Clarify the storage conditions of the drug substance and submit stability studies data accordingly. • As the only processing done is filling, storage conditions of the drug product shall also be clarified and stability data of finished product shall also be submitted accordingly.	CoA of drug substance provided in DMF is for China Zone II while CoA submitted to applicant is as per Zone IVa that is why stability of drug substance is also submitted as per Zone IVa conditions. Storage conditions of the drug product is also as per Zone IVa.
4.	**1.5.6 & 3.2.S.4.5**	Cefradine for Injection monograph is available in USP and BP. CoA of drug substance states that the material complies with USP43. As the only processing done is filling, justify your claim how the drug product complies in-house specifications instead of USP.	Cephradine for injection is no longer official in 2023 in online USP so that is why we have claimed finished product specifications as in-house.

Decision: Registration Board approved the applications of Ceframit 250mg IV/IM Injection, Ceframit 500mg IV/IM Injection & Ceframit 1g IV/IM Injection.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitmentsubmitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

CLB in its 292nd meeting held on 04th October, 2023 has considered and approved the grant of one additional section as follows:
Syrup section (General)

319.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of GMP certificate dated 06-06-2022 based on inspection conducted on 18-02-2022. Firm has also submitted report of inspection for grant of additional section conducted on 13-09-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 25-10-2023 specifying Syrup (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID:HWW-XGP-MDYS Dated 05-12-2023.
	Details of fee submitted	PKR 75,000/- Deposit Slip No. 853695443
	The proposed proprietary name / brand name	**PROLEXA Oral Solution 1mg / 1mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1mL Contains: Escitalopram oxalate equivalent to Escitalopram ……..1mg
	Pharmacotherapeutic Group of (API)	SSRI
	Pharmaceutical form of applied drug	Transparent Oral liquid/solution
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	100mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEXAPRO Oral Solution (USFDA Approved)
	For generic drugs (me-too status)	New drug. Me-too is not available.
	Name and address of API manufacturer.	Shodhana Laboratories Private Limited, Plot No. 24, 25 & 26, Phase-1, IDA, Jeedimetla, Hyderabad, Jeedimatla-Phase I & II Village Quthbullapur (Mandal), Medchal – Malkajgiri District – 500 055, Telangana State, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference

		standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Lexapro 5mg/5ml oral solution of AbbVie. CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	Shodhana Laboratories Private Limited, Plot No. 24, 25 & 26, Phase-1, IDA, Jeedimetla, Hyderabad, Jeedimatla-Phase I & II Village Quthbullapur (Mandal), Medchal – Malkajgiri District – 500 055, Telangana State, INDIA.		
API Lot No.	EO-091/22		
Description of Pack (Container closure system)	Amber colored glass bottle with plastic cap and seal.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-GP-OS-PX-22013	RD-GP-OS-PX-22014	RD-GP-OS-PX-22015
Batch Size	20 bottles	20 bottles	20 bottles
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	21-12-2022	21-12-2022	21-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate dated 03-05-2023 issued by Drugs Control Administration, Government of Telangana, valid till 01-05-2024. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted clearance certificate dated 10-11-2022 for 20kg Escitalopram oxalate
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	----------	Evidence of availability of DRAP approved microbiology lab shall be submitted.	Copy of report of DML renewal inspection conducted on 25-03-2022 is submitted wherein it is stated that microbiology laboratory with buffers and equipment was present.
2.	**2.3.R.1.1**	Executed BMRs of stability batches shall be submitted.	Submitted.
3.	**3.2.P.1 & 3.2.P.4**	Composition of the Drug Product includes Glycerin, Sorbitol and Propylene Glycol. In light of DRAP's letter/advisory No.F.3-41/2023-QC dated 01-12-2023, applicant shall submit following details for the three excipients: Vendor name, vendor qualification report, specifications, CoAs by respective vendor(s) as well as in-house batch analysis results, including test results for EG and DEG impurities.	CoA submitted by M/s Genetics Pharmaceuticals includes satisfactory test results for EG and DEG impurities.
4.	**3.2.P.8**	Documents for the procurement of API *with approval from DRAP* shall be submitted.	Submitted.
5.	**3.2.P.8**	Stability studies *raw data* of drug product for six- month time point is submitted only. Applicant shall submit complete stability data (both real time and accelerated) of the drug product for at least 6 months.	Submitted.
6.		Batch size of stability batches is 20 bottles. What equipment was used to manufacture the batches? Justify the scientific rationale for the batch size and also submit utilization record of the stability batches.	Applicant has used R&D equipment for syrup manufacturing. One 100mL pack/bottle was used for testing at each time point during the stability studies and the batch size is sufficient for performing stability testing for at least 24 months, according to the consumption details

			submitted by the applicant.

Decision: Approved. Registration letter will be issued upon submission of "batch manufacturing record" and "batch release data at initial time point" of newly manufactured trial batches with batch size sufficient enough to perform complete stability studies as per prescribed quality standards, till the claimed shelf life along with commitment to perform complete stability studies on newly manufactured trial batches

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

320.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 06-06-2022 based on inspection conducted on 18-02-2022. Firm has also submitted report of inspection for grant of additional section conducted on 13-09-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 25-10-2023 specifying Syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27497 dated 23-11-2023
	Details of fee submitted	PKR 30,000/- Deposit Slip No. 499859691
	The proposed proprietary name / brand name	**CLIPSEL 10mg/ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Lacosamide……10mg
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Pharmaceutical form of applied drug	Transparent Oral liquid/solution
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	100mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	VIMPAT Oral Solution (USFDA Approved)
	For generic drugs (me-too status)	Lalap Syrup of M/s Genix Pharma Pvt Ltd, Karachi (Reg. No. 89376)

	Name and address of API manufacturer.	Venkata Narayana Active Ingredients Pvt. Ltd. Sy No. 69, Chandrapadiya Village, Vinjamur Mandal, Nellore District, Andhra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Lalap 10mg/ml oral solution of M/s Genix Pharma Pvt Ltd. CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	Venkata Narayana Active Ingredients Pvt. Ltd. Sy No. 69, Chandrapadiya Village, Vinjamur Mandal, Nellore District, Andhra Pradesh, India.
API Lot No.	LC0670920
Description of Pack (Container closure system)	Transparent clear oral solution filled in amber color glass bottle with plastic cap and sealing packed in specified unit carton along with a leaflet insert
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-GP-OS-CL-22016	RD-GP-OS-CL-22017	RD-GP-OS-CL-22018
Batch Size	20 Bottles	20 Bottles	20 Bottles
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	02-01-2023	02-01-2023	02-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Product Specific Inspection of the firm was conducted for Capsules Dexstom 30mg & 60mg, for which the inspection was conducted on 21 & 22-07-2020 and the report was presented in 297th meeting of Registration Board. The report confirms the following: i. Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License Retention certificate for License No.04/NL/AP/2008/B/R dated 18-01-2023 issued by Drugs Control Administration, Government of Andhra Pradesh. The certificate specifies that the License of the firm is valid till 17-01-2028. GMP certificate is the API manufacturer valid till 01-01-2024 is also submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. DX202110232 cleared on 03-12-2020 specifying 100Kg of Lacosamide. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	----------	Evidence of availability of DRAP approved microbiology lab shall be submitted.	Copy of report of DML renewal inspection conducted on 25-03-2022 is submitted wherein it is stated that microbiology laboratory with buffers and equipment was present.
2.	**3.2.S.4**	API manufacturer has claimed BP specifications. However, acceptance values of several tests given on CoA of drug substance	Revised CoA claiming that the API conforms to

		are not according to BP. Complete testing report as per BP has also not been submitted. Complete specifications and testing results of drug substance according to BP shall be submitted from API manufacturer as well as from drug product manufacturer.	in-house specifications has been submitted.
3.	**3.2.P.1**	Composition of product includes methyl paraben sodium as preservative. According to requirements of BP, the need for and the efficacy of the chosen preservative shall be demonstrated.	Submitted
4.	**3.2.P.1 & 3.2.P.4**	Composition of the Drug Product includes Glycerin and Sorbitol. In light of DRAP's letter/advisory No.F.3-41/2023-QC dated 01-12-2023, applicant shall submit following details for the three excipients: Vendor name, vendor qualification report, specifications, CoAs by respective vendor(s) as well as in-house batch analysis results, including test results for EG and DEG impurities.	CoA submitted by M/s Genetics Pharmaceuticals includes satisfactory test results for EG and DEG impurities.
5.	**3.2.P.8**	Batch size of stability batches is 20 bottles. What equipment was used to manufacture the batches? Justify the scientific rationale for the batch size and also submit utilization record of the stability batches.	Applicant has used R&D equipment for syrup manufacturing. One 100mL pack/bottle was used for testing at each time point during the stability studies and the batch size is sufficient for performing stability testing for at least 24 months, according to the consumption details submitted by the applicant.
6.	**3.2.P.8**	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Submitted

Decision: Approved. Registration letter will be issued upon submission of "batch manufacturing record" and "batch release data at initial time point" of newly manufactured trial batches with batch size sufficient enough to perform complete stability studies as per prescribed quality standards, till the claimed shelf life along with commitment to perform complete stability studies on newly manufactured trial batches

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

321.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 06-06-2022 based on inspection conducted on 18-02-2022. Firm has also submitted report of inspection for grant of additional section conducted on 13-09-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 25-10-2023 specifying Syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27498 dated 23-11-2023
	Details of fee submitted	PKR 30,000/- Deposit Slip No. 56025288.
	The proposed proprietary name / brand name	**GEOXIT 20mg/5ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Fluoxetine HCl……20mg
	Pharmacotherapeutic Group of (API)	SSRI
	Pharmaceutical form of applied drug	Transparent Oral liquid/solution
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	120mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PROZAC Oral Solution (USFDA Approved)
	For generic drugs (me-too status)	Depricap Liquid of M/s Nabi Qasim Industries Pvt Ltd, Karachi (Reg. No. 023907)
	Name and address of API manufacturer.	Palam Pharma Pvt. Ltd, Plot No. 12/C, Phase –I, GIDC, Vatva, Ahmedabad, District Ahmedabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, specifications,

		analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at accelerated conditions and stability study data of 2 batches of drug substance at real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Depricap 20mg/5ml oral solution of M/s Nabiqasim Industries Pvt Ltd. CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	Palam Pharma Pvt. Ltd, Plot No. 12/C, Phase –I, GIDC, Vatva, Ahmedabad, District Ahmedabad.		
API Lot No.	FX/2111012		
Description of Pack (Container closure system)	Yellow clear oral solution filled in amber color glass bottle with plastic cap and sealing packed in specified unit carton along with a leaflet insert		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-GP-OS-GE-22022	RD-GP-OS-GE-22023	RD-GP-OS-GE-22024
Batch Size	25 Bottles	25 Bottles	25 Bottles
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	19-01-2023	19-01-2023	19-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Product Specific Inspection of the firm was conducted for Capsules Dexstom 30mg & 60mg, for which the inspection was conducted on 21 & 22-07-2020 and the report was presented in 297th meeting of Registration

		Board. The report confirms the following: i. Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License Retention certificate for License No.G/25/1511 dated 20-01-2023 issued by Food & Drugs Control Administration, Gujarat State. The certificate specifies that the License of the firm is valid till 31-12-2027. GMP certificate of the API manufacturer valid till 26-09-2023 is also submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 20-11-2021 specifying 75Kg of Fluoxetine Hydrochloride. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	----------	Evidence of availability of DRAP approved microbiology lab shall be submitted.	Copy of report of DML renewal inspection conducted on 25-03-2022 is submitted wherein it is stated that microbiology laboratory with buffers and equipment was present.
2.	**1.5.2**	Label claim shall be changed as follows according to reference product approved by USFDA and DRAP, along with submission of prescribed fee: "Each 5ml Contains: Fluoxetine HCl equivalent to Fluoxetine base……20mg"	Typographical error. *Applicant shall submit prescribed fee for correction in label claim.*
3.	**3.2.P.1 & 3.2.P.4**	Composition of the Drug Product includes Glycerin (Source: Oleo Corp Pvt Ltd). In light of DRAP's letter/advisory No.F.3-41/2023-QC dated 01-12-2023, applicant shall submit following details for glycerin: Vendor qualification report, specifications, CoA by respective vendor(s) as well as in-house batch analysis results, including test results for EG and DEG impurities.	Submitted
4.	**3.2.P.8**	Batch size of stability batches is 25 bottles. What equipment was used to manufacture the batches? Justify the scientific rationale for the batch size and also submit utilization record of the stability batches.	Applicant has used R&D equipment for syrup manufacturing. One 100mL pack/bottle was used for testing at each

			time point during the stability studies and the batch size is sufficient for performing stability testing for at least 24 months, according to the consumption details submitted by the applicant.

Decision: Approved. Registration letter will be issued upon submission of "batch manufacturing record" and "batch release data at initial time point" of newly manufactured trial batches with batch size sufficient enough to perform complete stability studies as per prescribed quality standards, till the claimed shelf life along with commitment to perform complete stability studies on newly manufactured trial batches

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

322.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 06-06-2022 based on inspection conducted on 18-02-2022. Firm has also submitted report of inspection for grant of additional section conducted on 13-09-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 25-10-2023 specifying Syrup (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27499 dated 23-11-2023
	Details of fee submitted	PKR 75,000/- Deposit Slip No. 1244338063
	The proposed proprietary name / brand name	**PREQUEL 20mg/ml Oral Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Quetiapine Fumarate Eq. to Quetiapine…20mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Pharmaceutical form of applied drug	Oral liquid/suspension
	Reference to Finished product specifications	USP Specifications

	Proposed Pack size	100mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Quetiapine Rosemont 20mg/ml Oral Suspension (MHRA Approved)
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	M/s Hema Pharmaceutical Pvt Ltd Plot No 6201/A &B. G.I.D.C Opp EWAC Alloys, Ankleshwar-393 002, Dist- Bharuch
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Quetiapine Rosemont 20mg/ml Oral Suspension of M/s Rosemont Pharmaceutical Ltd. CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.
STABILITY STUDY DATA		

Manufacturer of API	M/s Hema Pharmaceutical Pvt Ltd Plot No 6201/A &B. G.I.D.C opp EWAC Alloys, Ankleshwar-393 002, Dist- Bharuch		
API Lot No.	21QF0041		
Description of Pack (Container closure system)	White to off white oral suspension filled in amber color glass bottle with plastic cap and sealing packed in specified unit carton along with a leaflet insert		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,1, 3, 6 (Months)		
Batch No.	RD-GP-OS-PQ-22019	RD-GP-OS-PQ-22020	RD-GP-OS-PQ-22021
Batch Size	20 Bottles	20 Bottles	20 Bottles
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	25-01-2023	25-01-2023	25-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Product Specific Inspection of the firm was conducted for Capsules Dexstom 30mg & 60mg, for which the inspection was conducted on 21 & 22-07-2020 and the report was presented in 297th meeting of Registration Board. The report confirms the following: Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate No. S-GMP &GLP/22073413 valid till 03/07/2024 issued by Food and Drug Control Administration, Gujrat
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EXP-138/21-22 cleared on 27-01-2022 specifying 125Kg of Quetiapine Fumarate. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	----------	Evidence of availability of DRAP approved microbiology lab shall be submitted.	Copy of report of DML renewal inspection conducted on 25-03-2022 is submitted wherein it is stated that microbiology laboratory with buffers

			and equipment was present.
2.	**1.5.2**	Label claim given in 1.5.2 shall be changed as follows according to reference product approved by MHRA, along with submission of prescribed fee: "Each ml contains: Quetiapine Fumarate Equivalent to Quetiapine…20mg "	It is a typographical error. Applicant has changed label claim according to reference product. *Full fee of registration shall be submitted as prescribed for pre-registration variation (correction of composition as per reference regulatory authority's product).*
3.	**1.5.6**	Pharmacopoeial reference of applied product stated in 1.5.6 is USP. However, product monograph is not present in USP. Finished product specifications shall be changed along with submission of prescribed fee.	It is a typographical error. Applicant has changed product specifications to in-house specifications. *Prescribed fee for pre-registration variation shall be submitted.*
4.	**3.2.P.1 & 3.2.P.4**	Composition of the Drug Product includes Propylene Glycol. In light of DRAP's letter/advisory No.F.3-41/2023-QC dated 01-12-2023, applicant shall submit following details for the excipient: Vendor name, vendor qualification report, specifications, CoAs by respective vendor(s) as well as in-house batch analysis results, including test results for EG and DEG impurities.	Submitted.
5.	**3.2.P.8**	According to SmPC of reference product published by MHRA, the finished product storage condition is as follows: "Store in a refrigerator (2 – 8°C)" However, the stability studies for the applied product have been conducted at the following conditions: "Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH" Justification and complete supporting data shall be submitted.	Stability studies report and supporting data is submitted for following storage conditions: "Real time: 5°C ± 3°C, Accelerated: 25°C ± 2°C / 60% ± 5%RH"
6.	**3.2.P.8**	Batch size of stability batches is 20 bottles. What equipment was used to manufacture the batches? Justify the scientific rationale for the batch size.	Applicant has used R&D equipment for syrup manufacturing. One 100mL pack/bottle was used for testing at each time point during the stability studies and the batch size is sufficient for performing stability testing for at least 24 months, according to the consumption details

				submitted by the applicant.

Decision: Approved. Registration letter will be issued upon submission of "batch manufacturing record" and "batch release data at initial time point" of newly manufactured trial batches with batch size sufficient enough to perform complete stability studies as per prescribed quality standards, till the claimed shelf life along with commitment to perform complete stability studies on newly manufactured trial batches

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

323.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 06-06-2022 based on inspection conducted on 25-03-2022. Firm has also submitted report of inspection for grant of additional section conducted on 13-09-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 25-10-2023 specifying Syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27661 dated 27-11-2023
	Details of fee submitted	PKR 30,000/- Deposit Slip No. 25086763
	The proposed proprietary name / brand name	**Attentra 4mg/ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Atomoxetine……4mg
	Pharmacotherapeutic Group of (API)	Psychoanaleptics, Centrally acting sympathomimetics
	Pharmaceutical form of applied drug	Transparent Oral liquid/solution
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	100mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	STRATTERA 4mg / mL (MHRA Approved)
	For generic drugs (me-too status)	Not available.

	Name and address of API manufacturer.	M/s RL Fine Chem Pvt. Ltd, Plot No. IP No. 27-29, Parts of Sy Nos: 18, 273, 274 & 313 KIADB Industrial area, I Phase, Kudumalakunte village, Gowribidanur Taluk, Chickkaballapura District, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validaation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product Strattera 4mg/ml oral solution of M/s Eli Lilly & Company Ltd. CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s RL Fine Chem Pvt. Ltd, Plot No. IP No. 27-29, Parts of Sy Nos: 18, 273, 274 & 313 KIADB Industrial area, I Phase, Kudumalakunte village, Gowribidanur Taluk, Chickkaballapura District, India.
API Lot No.	ATM/007
Description of Pack	Clear transparent clear oral solution filled in amber color glass bottle with plastic

(Container closure system)	cap and sealing packed in specified unit carton along with a leaflet insert		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-GP-OS-AT-22007	RD-GP-OS-AT-22008	RD-GP-OS-AT-22009
Batch Size	20 Bottles	20 Bottles	20 Bottles
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	21-10-2022	28-10-2022	28-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Product Specific Inspection of the firm was conducted for Capsules Dexstom 30mg & 60mg, for which the inspection was conducted on 21 & 22-07-2020 and the report was presented in 297th meeting of Registration Board. The report confirms the following: Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License retention letter No. DCD/MFG/SR-1045/2021-2022 issued by Drugs Control Department, Government of Karnataka for License No. KTK/25/653/2016. The certificate specifies that the license is valid till 30-11-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. RLGB/E/0245 cleared on 01-01-2021 specifying 20Kg of Atomoxetine Hydrochloride. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.4.1**	Applicant has applied as generic product whereas the applied formulation is not already registered by DRAP (me-too is not available). However, same product is approved in 324th meeting of Registration Board and registration letter is not yet issued. Differential fee (Rs. 45,000) for New Drug Product (if applicable at the time of issuance of registration letter) shall be submitted.	Applicant has submitted differential fee of Rs. 45000 (DS No. 925365918873) is submitted.

	2.	**1.5.2**	Label claim given in 1.5.2 and BMRs is different. Label claim shall be changed as follows according to reference product approved by MHRA, along with submission of prescribed fee: "Each ml contains: Atomoxetine HCl equivalent to Atomoxetine ……4mg"	Only label claim in 1.5.2 is not as per reference product whereas product composition in BMR is according to reference product. Typographical error in label claim is revised as follows along with submission of Rs. 7500 pre-registration fee.
	3.	**3.2.S.7**	Long term stability studies data for API is submitted at 30°C ± 2°C / 65% ± 5% RH for 12 months. Real time stability studies data and report shall be submitted for complete shelf life of the API i.e. 60 months.	Submitted.
	4.	**3.2.P.1**	Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.	Submitted.
	5.	**3.2.P.1 & 3.2.P.4**	Composition of the Drug Product includes Sorbitol and Propylene Glycol. In light of DRAP's letter/advisory No.F.3-41/2023-QC dated 01-12-2023, applicant shall submit following details for the two excipients: Vendor name, vendor qualification report, specifications, CoAs by respective vendor(s) as well as in-house batch analysis results, including test results for EG and DEG impurities.	CoAs of Sorbitol and Proplylene glycol are submitted. The batch analysis results, include test results for EG and DEG impurities.
	6.	**3.2.P.8**	Documents for the procurement of API *with approval from DRAP (*ADC attested invoice) shall be submitted.	Submitted.

Decision: Approved. Registration letter will be issued upon submission of "batch manufacturing record" and "batch release data at initial time point" of newly manufactured trial batches with batch size sufficient enough to perform complete stability studies as per prescribed quality standards, till the claimed shelf life along with commitment to perform complete stability studies on newly manufactured trial batches

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

324.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of GMP certificate dated 06-06-2022 based on inspection conducted on 25-03-2022. Firm has also submitted report of inspection for grant of additional section conducted on 13-09-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 25-10-2023 specifying Syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27496 dated 23-11-2023
	Details of fee submitted	PKR 30,000/- Deposit Slip No. 156350637164
	The proposed proprietary name / brand name	**Vepridone Oral Solution 1mg/mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1mL Contains: Risperidone……1mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Pharmaceutical form of applied drug	Clear, Transparent Oral liquid
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	100mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Risperdal (USFDA Approved)
	For generic drugs (me-too status)	Persch Oral Solution of M/s Barret Hodgson Pakistan Pvt Ltd, Karachi. (Registration No. 32477)
	Name and address of API manufacturer.	Venkata Narayana Active Ingredients Pvt. Ltd. Sy No. 69, Chandrapadiya Village, Vinjamur Mandal, Nellore District, Andhra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Risp 5mg/5ml oral solution of M/s Adamjee Pharmaceuticals Pvt Ltd, Karachi. CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	Venkata Narayana Active Ingredients Pvt. Ltd. Sy No. 69, Chandrapadiya Village, Vinjamur Mandal, Nellore District, Andhra Pradesh, India.		
API Lot No.	RN0030321		
Description of Pack (Container closure system)	Transparent clear oral liquid filled in amber color glass bottle with plastic cap and sealing packed in specified unit carton along with a leaflet insert		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-GP-OS-VP-22004	RD-GP-OS-VP-22005	RD-GP-OS-VP-22006
Batch Size	20 Bottles	20 Bottles	20 Bottles
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	18-10-2022	18-10-2022	18-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Product Specific Inspection of the firm was conducted for Capsules Dexstom 30mg & 60mg, for which the inspection was conducted on 21 & 22-07-2020 and the report was presented in 297th meeting of Registration Board. The report confirms the following: Firm has demonstrated audit trail reports of testing.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License retention letter issued by Drugs Control Administration, Government of Andhra Pradesh for License No. 04/NL/AP/2008/B/R. The certificate specifies that the license is valid till 17-01-2028.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 30-08-2021 specifying 300g of Risperidone. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**----------**	Evidence of availability of DRAP approved microbiology lab shall be submitted.	Copy of report of DML renewal inspection conducted on 25-03-2022 is submitted wherein it is stated that microbiology laboratory with buffers and equipment was present.
2.	**3.2.S.7**	Long term stability studies data for API is submitted at 30°C ± 2°C / 75% ± 5% RH for 48 months. Real time stability studies data and report shall be submitted as per Zone Iva conditions i.e 30°C ± 2°C / 65% ± 5% RH for complete shelf life of the drug substance.	Submitted.
3.	**3.2.P.1**	Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.	Submitted.
4.	**3.2.P.8**	Batch size of stability batches is 20 bottles. What equipment was used to manufacture the batches? Justify the scientific rationale for the batch size and also submit utilization record of the stability batches.	Applicant has used R&D equipment for syrup manufacturing. One 100mL pack/bottle was used for testing at each time point during the stability studies and the batch size is sufficient for performing stability testing for at least 24 months, according to the consumption details submitted by the applicant.

Decision: Approved. Registration letter will be issued upon submission of "batch manufacturing record" and "batch release data at initial time point" of newly manufactured trial batches with batch size sufficient enough to perform complete stability studies as per prescribed quality standards, till the

	claimed shelf life along with commitment to perform complete stability studies on newly manufactured trial batches • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
325.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd.** **14 km Adyala Road Post Office Dahgal, Rawalpindi.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Dahgal, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-12-2021 based on inspection conducted on 04-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of revised section dated 27-02-2023 specifying Soft Gelatin Capsule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No HQH-8E1-ELN7 dated 22-02-2024
	Details of fee submitted	PKR 30,000/- Deposit Slip No. 1091814695
	The proposed proprietary name / brand name	**Isotin 40mg Soft gelatin capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Isotretinoin……40mg
	Pharmacotherapeutic Group of (API)	Anti-acne preparations for systemic use, Retinoids for treatment of acne
	Pharmaceutical form of applied drug	Oral soft gel capsule
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	3 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA & MHRA Approved
	For generic drugs (me-too status)	Maxinoin Capsule 40mg of M/s Maxitech Pharma (Pvt) Ltd (Registration No.108920)
	Name and address of API manufacturer.	M/s Horster Biotek Pvt Ltd Khasra No. 259, Plot No. 1&2, Sukhliya Sanwer RD Industrial Area Indore – 452015(India).

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, working standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence and Comparative Dissoultion Profile of their product against the comparator product Maxinoin 40mg Soft gel capsules of M/s Maxitech Pharma (Pvt) Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Horster Biotek Pvt Ltd Khasra No. 259, Plot No. 1&2, Sukhliya Sanwer RD Industrial Area Indore –452015(India).
API Lot No.	HBPL/ISO/22-23/007
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 3 months Accelerated: 3 months
Frequency	Accelerated: 0, 1, 3 (Months) Real Time: 0, 3 (Months)

Batch No.	073NS01	073NS02	073NS03
Batch Size	2000 capsules	2000 capsules	2000 capsules
Manufacturing Date	04-2023	04-2023	04-2023
Date of Initiation	20-04-2023	20-04-2023	20-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted for relevant unit of API manufacturer.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 05-04-2023 specifying 1kg of Isotretinoin. The certificate is issued by AD (I&E) DRAP, Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**2.3.S.4.4 & 3.2.S.4.4**	CoAs of three batches of API are submitted i.e. 2009065, IST-20230706 (generated by Chongqing Huapont Pharm. Co. Ltd) and HBPL/ISO/22-23/007 (generated by Horster Biotek). Clarification shall be submitted regarding the manufacturer of drug substance along with submission of following: • CoA (from manufacturer and applicant) of the batch of drug substance used in the manufacturing of stability batches. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Batch No. of API used in the manufacturing of stability batches is HBPL/ISO/22-23/007 manufcatured by M/s Horster Biotek Pvt Ltd Khasra No. 259, Plot No. 1&2, Sukhliya Sanwer RD Industrial Area Indore – 452015(India). CoAs (from manufacturer and applicant) are subnmitted. Approval of API/ DML/GMP certificate of *relevant site* of API manufacturer issued by concerned regulatory authority of country of origin.
2.	**3.2.P.8**	Results and raw data of real time and accelerated stability studies of FPP shall be submitted for 6 month time point	Submitted.

	3.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Submitted.
Decision: Deferred for submission of valid DML/GMP certificate of drug substance manufacturer issued by the relevant authority of country of origin.				

Agenda of Evaluator PEC-XXIV

Case No. : Registration applications of New Section of Human drugs on Form 5-F (Local)

The Central Licensing Board in its 285th meeting held on 17th & 18th March, 2022 has considered and approved additional new section i.e. Dry Powder Injection (Cephalosporin) of M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway, Karachi, under DML No.000809(Formulation), vide letter No. F. 2-10/2002-Lic(Vol-I) dated 29th April, 2022.

Following 10 applications have been submitted by the firm for registration: -

326.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway, Karachi.**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 20842 dated 23-08-2023 Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Cefobactam 2g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefoperazone Sodium Equivalent to Cefoperazone.....1gm Sulbactam Sodium Equivalent to Sulbactam …….. 1gm
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	y powder for injection
	Reference to Finished product specifications	JP Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Sulperazone Intravenous Injection 2g (PMDA Japan Approved)
	For generic drugs (me-too status)	Sulperazone 2g Injection of M/s Bio labs, (Reg.No. 054581)
	Name and address of API manufacturer.	**(Cefoperazone Sodium)** Lucent drugs Pvt Ltd Factory: Sy. No. 10, Gaddapotharam Village, Jinnaram Mandal, sanga Reddy (Dist.)Telanga-502325- India **(Sulbactam Sodium)** Hubei Hongyuan pharmaceutical Technology 428 Yishui North Road Fengshan Town Luotian County Huanggang, 438600 China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Cebac 2 g manufactured by Bosch Pharmaceuticals Pvt. Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug

		product.		
STABILITY STUDY DATA				
Manufacturer of API		**(Cefoperazone Sodium)** Lucent drugs Pvt Ltd Factory: Sy. No. 10, Gaddapotharam Village, Jinnaram Mandal, sanga Reddy (Dist.)Telanga-502325- India		
API Lot No.		**CS/32/15, CS/35/15, CS/38/15**		
Manufacturer of API		**(Sulbactam Sodium)** Hubei Hongyuan pharmaceutical Technology 428 Yishui North Road Fengshan Town Luotian County Huanggang, 438600 China		
API Lot No.		13072016, 15072016, 18072016		
Description of Pack (Container closure system)		Vial		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		IB-116	IB-119	IB-121
Batch Size		500 Vials	500 Vials	500 Vials
Manufacturing Date		02-2022	02-2022	02-2022
No. of Batches		03		
327.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**		
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi		
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)		
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.		
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)		
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)		
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales		
	Dy. No. and date of submission & Details of fee submitted	Dy.No 20821 dated 23-08-2023 Rs.30,000/- dated 16-09-2022		
	The proposed proprietary name / brand name	**Cefobactam 1g Injection**		

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefoperazone Sodium Equivalent to Cefoperazone.....500mg Sulbactam Sodium Equivalent to Sulbactam.....500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	y powder for injection
	Reference to Finished product specifications	JP Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulperazone Intravenous Injection 1g (PMDA Japan Approved)
	For generic drugs (me-too status)	Sulperazone 1g Injection of M/s Bio labs, (Reg.No. 054580)
	Name and address of API manufacturer.	**(Cefoperazone Sodium)** Lucent drugs Pvt Ltd Factory: Sy. No. 10, Gaddapotharam Village, Jinnaram Mandal, sanga Reddy (Dist.)Telanga-502325- India **(Sulbactam Sodium)** Hubei Hongyuan pharmaceutical Technology 428 Yishui North Road Fengshan Town Luotian County Huanggang, 438600 China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Cebac 1 g manufactured by Bosch Pharmaceuticals Pvt. Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**(Cefoperazone Sodium)** Lucent drugs Pvt Ltd Factory: Sy. No. 10, Gaddapotharam Village, Jinnaram Mandal, sanga Reddy (Dist.)Telanga-502325- India		
API Lot No.	**CS/32/15, CS/35/15, CS/38/15**		
Manufacturer of API	**(Sulbactam Sodium)** Hubei Hongyuan pharmaceutical Technology 428 Yishui North Road Fengshan Town Luotian County Huanggang, 438600 China.		
API Lot No.	13072016, 15072016, 18072016		
Description of Pack (Container closure system)	Vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-101	IB-103	IB-105
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	02-02-2022	03-02-2022	04-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Lucent Drugs pvt Ltd GMP Certificate (No. 7774/E1/2020 dated 29-01-2020 issued by Drug Control Administration Govt of Telangana). The certificate specifies that the firm is operating at satisfactory level of GMP compliance.

		Firm has submitted copy of Hubei Hong yuan Technology GMP Certificate (No. HB2020424 dated 31-07-2020 issued by China Food and Drugs Administration). The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

- Clarification shall be submitted regarding applied formulation, whether manufactured from ready to fill pre-mixed sterile powder of Cefoperazone sodium + Sulbactam sodium or is formulated by mixing and filling of Cefoperazone sodium & Sulbactam sodium at M/s Mission Pharmaceuticals.
- Batch manufacturing date declared in stability summary sheets is earlier to the date of grant of additional section of "Dry Powder Injection Cephalosporin" by Licensing Division. Justification shall be submitted in this regard.
- Following shall be submitted:
  i. Analytical record of stability studies supported by respective documents like chromatograms, COA etc.
  ii. Compliance Record of HPLC software 21CFR & audit trail reports on product testing
  iii. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).
  iv. Documents confirming procurement of drug substance.
  v. Compete batch manufacturing record for three stability batches shall be submitted.

Decision: Registration Board deferred the cases of Cefobactam 2g Injection & Cefobactam 1g Injection for submission of reply to the above cited shortcomings

328.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission DETAILS of fee submitted	Dy.No 22342 dated 11-09-2023 Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Cefobactam 1.5g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefoperazone Sodium Equivalent to Cefoperazone.....1g Sulbactam Sodium Equivalent to Sulpactam.....500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Dry powder for injection
	Reference to Finished product specifications	(JP Specification)
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Magnex Forte 1.5g Injection (USFDA Approved)
	For generic drugs (me-too status)	Magnex Forte 1.5g Injection of M/s Pfizer.
	Name and address of API manufacturer.	**(Cefoperazone Sodium)** Lucent drugs Pvt Ltd Factory: Sy. No. 10, Gaddapotharam Village, Jinnaram Mandal, sanga Reddy (Dist.)Telanga-502325- India **(Sulbactam Sodium)** Hubei Hongyuan pharmaceutical Technology 428 Yishui North Road Fengshan Town Luotian County Huanggang, 438600 China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches

	(Conditions & duration of Stability studies)	of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Cebac 1 g manufactured by Bosch Pharmaceuticals pvt Ltd Comparative Dissolution Profile: N/A.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**(Cefoperazone Sodium)** Lucent drugs Pvt Ltd Factory: Sy. No. 10, Gaddapotharam Village, Jinnaram Mandal, sanga Reddy (Dist.)Telanga-502325- India		
API Lot No.	**CS/32/15, CS/35/15, CS/38/15**		
Manufacturer of API	**(Sulbactam Sodium)** Hubei Hongyuan pharmaceutical Technology 428 Yishui North Road Fengshan Town Luotian County Huanggang, 438600 China		
API Lot No.	13072016, 15072016, 18072016		
Description of Pack (Container closure system)	Vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-125	IB-127	IB-129
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	22-02-2022	23-02-2022	24-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Lucent Drugs pvt Ltd GMP Certificate (No. 7774/E1/2020 dated 29-01-2020 issued by Drug Control Administration Govt of Telangana). The certificate specifies that the firm is operating at satisfactory level of GMP compliance. Firm has submitted copy of Hubei Hong yuan Technology GMP Certificate (No. HB2020424 dated 31-07-2020 issued by China Food and Drugs Administration). The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

- Submit evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
- Submit evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm.
- Documents confirming procurement of drug substance.

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

329.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission Details of fee submitted	Dy.No 22339 dated 11-09-2023 Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Cefozone 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefoperazone Sodium Equivalent to Cefoperazone.....500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	hite to off white or pale buff crystalline powder. efozone injection is a sterile solution of Cefoperazone Sodium and a suitable osmolality adjusting substance in Water for Injection. It may contain a suitable buffer.
	Reference to Finished product specifications	(USP Specification)
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefobid 500mg Injection (USFDA Approved)
	For generic drugs (me-too status)	Cefobid 500mg Injection of M/s Pfizer, (Reg.No.013841)
	Name and address of API manufacturer.	Lucent drugs Pvt Ltd Factory: Sy. No. 10, Gaddapotharam Village, Jinnaram Mandal, sanga Reddy (Dist.)Telanga-502325- India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is

		conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Cefobid 500mg manufactured by Pfizer. Comparative Dissolution Profile: N/A.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Lucent drugs Pvt Ltd Factory: Sy. No. 10, Gaddapotharam Village, Jinnaram Mandal, sanga Reddy (Dist.)Telanga-502325- India		
API Lot No.	**CS/32/15, CS/35/15, CS/38/15**		
Description of Pack (Container closure system)	Vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-76	IB-77	IB-79
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	18-02-2022	21-02-2022	23-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Lucent Drugs pvt Ltd GMP Certificate (No. 7774/E1/2020 dated 29-01-2020 issued by Drug Control Administration Govt of Telangana).

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr No.	Observations	Firm's response
1.	Analytical record of stability studies supported by respective documents like chromatograms, COA etc. shall be submitted.	
2.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
3.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	
4.	Compete batch manufacturing record for three stability batches shall be submitted.	
5.	Documents confirming procurement of drug substance.	

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

330.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission & details of fee submitted	Dy.No 22340 dated 11-09-2023 Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Cefozone 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefoperazone Sodium Equivalent to Cefoperazone.....1g
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	hite to off white or pale buff crystalline powder. efozone injection is a sterile solution of Cefoperazone Sodium and a suitable osmolality adjusting substance in Water for Injection. It may contain a suitable buffer.
	Reference to Finished product specifications	(USP Specification)
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefobid 1g Injection (USFDA Approved)
	For generic drugs (me-too status)	Cefobid 1g Injection of M/s Pfizer, (Reg.No.008524)
	Name and address of API manufacturer.	Lucent drugs Pvt Ltd Factory: Sy. No. 10, Gaddapotharam Village, Jinnaram Mandal, sanga Reddy (Dist.)Telanga-502325- India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its

		description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Viperazone 1g manufactured by Kalmia Health Care Comparative Dissolution Profile: N/A.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Lucent drugs Pvt Ltd Factory: Sy. No. 10, Gaddapotharam Village, Jinnaram Mandal, sanga Reddy (Dist.) Telanga-502325- India		
API Lot No.	**CS/32/15, CS/35/15, CS/38/15**		
Description of Pack (Container closure system)	Vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-69	IB-72	IB-75
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	12-02-2022	14-02-2022	16-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Lucent Drugs pvt Ltd GMP Certificate (No. 7774/E1/2020 dated 29-01-2020 issued by Drug Control Administration Govt of Telangana). The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr No.	Observations	Firm's response
1.	Analytical record of stability studies supported by respective documents like chromatograms, COA etc. shall be submitted.	
2.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
3.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	
4.	Compete batch manufacturing record for three stability batches shall be submitted.	
5.	Documents confirming procurement of drug substance.	

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

331.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & details of fee submitted	Dy.No 20842 dated 23-08-2023 Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Ceftox 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefotaxime Sodium Equivalent to Cefotaxime.....500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics

	Pharmaceutical form of applied drug	hite to off white or pale buff crystalline powder. Ceftox injection is a sterile solution of Cefotaxime Sodium and a suitable osmolality adjusting substance in Water for Injection. It may contain a suitable buffer.
	Reference to Finished product specifications	(USP Specification)
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Claforan 500mg Injection (USFDA Approved)
	For generic drugs (me-too status)	Claforan 500mg Injection of M/s Sanofi Aventis Kline, (Reg.No. 020483)
	Name and address of API manufacturer.	Harbin Hejia Pharmaceutical Co., Ltd Economic & Technical Development Zone Shanghzhi City Heilongjiang-China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Claforan 500mg manufactured by Sanofi Aventis. Comparative Dissolution Profile: N/A.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Harbin Hejia Pharmaceutical Co., Ltd Economic & Technical Development Zone Shanghzhi City Heilongjiang-China		
API Lot No.	SN202004002, SN202004003. SN202004004		
Description of Pack (Container closure system)	Vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CF-135	CF-137	CF-139
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	01-02-2022	03-02-2022	05-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. HL2022004) dated 04-05-2022, issued by China Food & Drugs Administration. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr No.	Observations	Firm's response
1.	Analytical record of stability studies supported by respective documents like chromatograms, COA etc. shall be submitted.	
2.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
3.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	
4.	Compete batch manufacturing record for three stability batches shall be submitted.	
5.	Documents confirming procurement of drug substance.	

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

332.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & details of fee submitted	Dy.No 20843 dated 23-08-2023 Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Ceftox 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefotaxime Sodium Equivalent to Cefotaxime.....1g
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	hite to off white or pale buff crystalline powder. Ceftox injection is a sterile solution of Cefotaxime Sodium and a suitable osmolality adjusting substance

		in Water for Injection. It may contain a suitable buffer.
	Reference to Finished product specifications	(USP Specification)
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Claforan 1g Injection (USFDA Approved)
	For generic drugs (me-too status)	Claforan 1g Injection of M/s Sanofi Aventis Kline, (Reg.No. 006058)
	Name and address of API manufacturer.	Harbin Hejia Pharmaceutical Co., Ltd Economic & Technical Development Zone Shanghzhi City Heilongjiang-China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Claforan 1g manufactured by sanofi Aventis. Comparative Dissolution Profile: N/A.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug

		product.

STABILITY STUDY DATA			
Manufacturer of API	Harbin Hejia Pharmaceutical Co., Ltd Economic & Technical Development Zone Shanghzhi City Heilongjiang-China		
API Lot No.	SN202004002, SN202004003. SN202004004		
Description of Pack (Container closure system)	Vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CF-141	CF-143	CF-145
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	03-02-2022	05-02-2022	07-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. HL2022004) dated 04-05-2022, issued by China Food & Drugs Administration. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr No.	Observations	Firm's response
1.	Analytical record of stability studies supported by respective documents like chromatograms, COA etc. shall be submitted.	
2.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
3.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	
4.	Compete batch manufacturing record for three stability batches shall be submitted.	
5.	Documents confirming procurement of drug substance.	

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

333.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 22343 dated 11-09-2023 Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Misapime 2gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime Hydrochloride Equivalent to Cefepime.....2gm
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	y powder for injection
	Reference to Finished product specifications	(USP Specification)
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved

	For generic drugs (me-too status)	Cefstar 2gm Injection of M/s, Barrette Hodgson (Reg.No. 089284)
	Name and address of API manufacturer.	Akum Life Sciences Limited Unit I : VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Akum Life Sciences Limited Unit I : VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)
API Lot No.	CPM/017/15, CPM/019/15, CPM/021/15

Description of Pack (Container closure system)	Vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-005	IB-006	IB-012
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
No. of Batches	03		

334.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 20836 dated 23-08-2023 Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Misapime 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime Hydrochloride Equivalent to Cefepime.....1gm
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	y powder for injection
	Reference to Finished product specifications	(USP Specification)
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Cefstar 1gm Injection of M/s, Barrette Hodgson (Reg.No. 030954)
	Name and address of API manufacturer.	Akum Life Sciences Limited

		Unit I : VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Cefstar 1gm manufactured by Barrett Hodgson Pakistan Pvt Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Akum Life Sciences Limited Unit I : VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)
API Lot No.	CPM/017/15, CPM/019/15, CPM/021/15
Description of Pack	Vial

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-007	IB-009	IB-010
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
No. of Batches	03		

335.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi**
	Name, address of Manufacturing site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry Powder Injection Cephalosporin (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 20835 dated 23-08-2023 Rs.30,000/- dated 16-09-2022
	The proposed proprietary name / brand name	**Misapime 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime Hydrochloride Equivalent to Cefepime.....500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	y powder for injection
	Reference to Finished product specifications	(USP Specification)
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Renapime 500mg Powder for solution for injection/infusion (Rena Science) (USFDA Approved)
	For generic drugs (me-too status)	Cefstar 500mg Injection of M/s, Barrette Hodgson (Reg.No. 030953)

	Name and address of API manufacturer.	Akum Life Sciences Limited Unit I : VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Cefstar 500mg manufactured by Barrett Hodgson Pakistan Pvt Ltd. Comparative Dissolution Profile: N/A.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Akum Life Sciences Limited Unit I : VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)

API Lot No.	CPM/017/15, CPM/019/15, CPM/021/15		
Description of Pack (Container closure system)	Vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IB-001	IB-002	IB-003
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	02-02-2022	03-02-2022	03-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. Pb.2021/4570) dated 19-07-2021, issued by Food & Drugs Administration Punjab India. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

- Submitted formulation does not reflect the content of arginine, as per innovator drug product. Clarification shall be submitted in this regard.
- Following shall be submitted:

vii. Analytical record of stability studies supported by respective documents like chromatograms, COA etc.
viii. Compliance Record of HPLC software 21CFR & audit trail reports on product testing
ix. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).
x. Documents confirming procurement of drug substance.
xi. Compete batch manufacturing record for three stability batches shall be submitted.

Decision: Registration Board deferred the cases of Misapime 2gm Injection, Misapime 1gm Injection & Misapime 500mg Injection for submission of reply to the above cited shortcomings

Case No. : Registration applications of New Section of Human drugs on Form 5-F (Local)

The Central Licensing Board in its 278th meeting held on 10th & 11th December, 2020 has considered and approved the grant of following four additional new sections to M/s Wezen Pharmaceuticals, Plot No. 23 & 24, SI, Industrial Estate, Rawat., under DML No.000882(Formulation), vide letter No. F. 1-30/2014-Lic. dated 30th December, 2020.

Sr. No.	Sections
1.	Tablet (General)
2.	Capsule (General)
3.	**Sachet (General)**
4.	Ointment/Creams/Gel (General)

Following 03 applications have been submitted by the firm for registration: -

336.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-I, Industrial Estate, Rawat. (DML#000882)**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-I, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30-12-2020 specifying Sachet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 26280 dated 31-10-2023
	Details of fee submitted	Rs.30,000/- dated 18-09-2023 Slip # 0292275887
	The proposed proprietary name / brand name	**Riseka 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Racecadotril…10mg
	Pharmacotherapeutic Group of (API)	Antidarrheal
	Pharmaceutical form of applied drug	white to almost white powder.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Hidrasec 10mg Sachet of M/s Abbott Laboratories Pakistan Limited.

	Name and address of API manufacturer.	**Symed Labs Limited** Unit-II :Plot No. 25/B, Phase III, I.D.A, Jeedimetla (Village), Quthbullalpur (Mandal), Medchal-Malkajgiri (Dist) -500 055 Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Hidrasec 10mg Sachet of M/s Abbott Laboratories Pakistan Limited. Comparative Dissolution Profile: Not performed.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	**Symed Labs Limited** Unit-II :Plot No. 25/B, Phase III, I.D.A, Jeedimetla (Village), Quthbullalpur (Mandal), Medchal-Malkajgiri (Dist) -500 055 Telangana, India.		
API Lot No.	2RAC0480622		
Description of Pack (Container closure system)	Sachet		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-04	T-05	T-06
Batch Size	1500 Sachet	1500 Sachet	1500 Sachet
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	12-01-2023	12-01-2023	12-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Drug substance clearance is in the name of M/s Weather fold Pharmaceuticals, Hattar instead of M/s Wezen Pharmaceuticals, Rawat.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

- Renewal status of the DML shall be submitted.
- Latest GMP certificate of the M/s Wezen Pharmaceuticals, Rawat shall be submitted.
- Drug substance clearance is in the name of M/s Weather fold Pharmaceuticals, Hattar instead of M/s Wezen Pharmaceuticals, Rawat, clarification shall be submitted.

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

337.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-I, Industrial Estate, Rawat. (DML#000882)**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-I, Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30-12-2020 specifying Sachet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 26281 dated 31-10-2023
	Details of fee submitted	Rs.30,000/- dated 18-09-2023 Slip # 262247312450
	The proposed proprietary name / brand name	**Riseka 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Racecadotril…30mg
	Pharmacotherapeutic Group of (API)	Antidarrheal
	Pharmaceutical form of applied drug	white to almost white powder.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Hidrasec 30mg Sachet of M/s Abbott Laboratories Pakistan Limited.
	Name and address of API manufacturer.	**Symed Labs Limited** Unit-II :Plot No. 25/B, Phase III, I.D.A, Jeedimetla (Village), Quthbullalpur (Mandal), Medchal-Malkajgiri (Dist) -500 055 Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Hidrasec 30mg Sachet of M/s Abbott Laboratories Pakistan Limited. Comparative Dissolution Profile: Not performed.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Symed Labs Limited** Unit-II :Plot No. 25/B, Phase III, I.D.A, Jeedimetla (Village), Quthbullalpur (Mandal), Medchal-Malkajgiri (Dist) -500 055 Telangana, India.		
API Lot No.	2RAC0480622		
Description of Pack (Container closure system)	Capsules in blister of 16's.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-07	T-08	T-09
Batch Size	1500 Sachet	1500 Sachet	1500 Sachet
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	12-01-2023	12-01-2023	12-01-2023
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Drug substance clearance is in the name of M/s Weather fold Pharmaceuticals, Hattar instead of M/s Wezen Pharmaceuticals, Rawat.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

- Renewal status of the DML shall be submitted.
- Latest GMP certificate of the M/s Wezen Pharmaceuticals, Rawat shall be submitted.
- Drug substance clearance is in the name of M/s Weather fold Pharmaceuticals, Hattar instead of M/s Wezen Pharmaceuticals, Rawat, clarification shall be submitted in this regard.
- Comparative dissolution not performed for granular powder. Justification shall be submitted.

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

338.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-I, Industrial Estate, Rawat. (DML#000882)**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-I, Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30-12-2020 specifying Sachet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 26282 dated 31-10-2023
	Details of fee submitted	Rs.30,000/- dated 18-09-2023 Slip # 4657522497
	The proposed proprietary name / brand name	**Riseka 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Racecadotril…100mg
	Pharmacotherapeutic Group of (API)	Antidarrheal

	Pharmaceutical form of applied drug	white to almost white powder filled in hard gelatin capsule.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1*16's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Hidrasec 100mg Capsule of M/s Abbott Laboratories Pakistan Limited.
	Name and address of API manufacturer.	**Symed Labs Limited** Unit-II :Plot No. 25/B, Phase III, I.D.A, Jeedimetla (Village), Quthbullalpur (Mandal), Medchal-Malkajgiri (Dist) -500 055 Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical & equivalence comparative dissolution profile of their product against Hidrasec 100mg Capsules of M/s Abbott Laboratories Pakistan Limited.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Symed Labs Limited** Unit-II :Plot No. 25/B, Phase III, I.D.A, Jeedimetla (Village), Quthbullalpur (Mandal), Medchal-Malkajgiri (Dist) -500 055 Telangana, India.		
API Lot No.	2RAC0480622		
Description of Pack (Container closure system)	Sachet		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1200 Capsules	1200 Capsules	1200 Capsules
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	12-01-2023	12-01-2023	12-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Drug substance clearance is in the name of M/s Weather fold Pharmaceuticals, Hattar instead of M/s Wezen Pharmaceuticals, Rawat.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

- Renewal status of the DML shall be submitted.
- Latest GMP certificate of the M/s Wezen Pharmaceuticals, Rawat shall be submitted.
- Drug substance clearance is in the name of M/s Weather fold Pharmaceuticals, Hattar instead of M/s Wezen Pharmaceuticals, Rawat, clarification shall be submitted in this regard.

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

Case No. : Registration applications of New Section of Human drugs on Form 5-F (Local)

The Central Licensing Board in its 290th meeting held on 28th April, 2023 has considered and approved the grant of DML No.000973 (Formulation) to M/s **Al Barakat Pharmaceutical Industries**, **Plot # B/66-A, S.I.T.E, Nooriabad, Jamshoro** vide letter No. F. 2-7/2017-Lic. dated 18th October, 2023 for following four sections as under

Sr. No.	Sections
5.	Liquid Ampoule (General)
6.	Liquid Injectable Vial SVP (General)
7.	**Eye/Ear Drop (General)**
8.	Eye Ointment (General)

Following 03 applications have been submitted by the firm for registration: -

339.	**Name, address of Applicant / Marketing Authorization Holder**	M/s **Al Barakat Pharmaceutical Industries**, **Plot # B/66-A, S.I.T.E, Nooriabad, Jamshoro**
	Name, address of Manufacturing site.	**M/s Al Barakat Pharmaceutical Industries, Plot # B/66-A, S.I.T.E, Nooriabad, Jamshoro**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML granted on 18-10-2023 .
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-7/2017-Lic. dated 18th October, 2023 specifying Liquid Injectable Vial SVP (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID No U38-37A-ZXG4 dated 12-02-2024
	Details of fee submitted	Rs.30,000/- dated 02-12-2023
	The proposed proprietary name / brand name	**Alpara Infusion 1gm/100ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Paracetamol 1gm
	Pharmacotherapeutic Group of (API)	Antipyretic
	Pharmaceutical form of applied drug	white to almost white powder.
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Provas Infusion of M/s Sami

	Name and address of API manufacturer.	M/s. Saakh Pharma Pvt. Ltd. Plot # C-7/1, North West Industrial Zone, Port Qasim, Karachi, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Provas Infusion of M/s Sami
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s. Saakh Pharma Pvt. Ltd. Plot # C-7/1, North West Industrial Zone, Port Qasim, Karachi, Pakistan		
API Lot No.	23GN6-10094		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PAR-TB-001	PAR-TB-002	PAR-TB-003
Batch Size	30L	30L	30L
Manufacturing Date	05-2023	05-2023	05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate issued by Additional Director I&E, DRAP Karachi issued on basis of inspection conducted on 7-10-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Frim has submitted loan letter from M/s Ahson Drug Co. T/1 SITE Tando Adam
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr No.	Observations	Firm's response
1.	Finished product specifications applied in Form 5F are BP Specifications whereas no monograph is available for the applied formulation, furthermore, in testing methods Albarkat Specs. are mentioned, justification shall be submitted in this regard.	Firm has declared it as typing mistake and has submitted finished drug product specifications as A Barkat specifications.
2.	Drug product analytical method verification studies have not been submitted.	Submitted
3.	Batch size justification shall be submitted against the number of units required to complete the stability studies till claimed shelf life.	Submitted
4.	Compete batch manufacturing record for three stability batches shall be submitted.	
5.	Documents confirming procurement of drug substance.	

Decision: Deferred for submission of following:

- **Compete batch manufacturing record for three stability batches**
- **Documents confirming procurement of drug substance.**

Agenda of Evaluator PEC-XXV

Case no.01 Registration applications of New DML (Veterinary)

a. New Cases

I. M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.

CLB in its 294th meeting held on 27th December, 2023 has considered and approved the grant of DML by way of formulation with following sections:

1. Oral Powder-I (General) Vet. Section
2. Oral Powder-II (General) Vet. Section
3. Oral Liquid-I (General) Vet. Section
4. Oral Liquid-II (General) Vet. Section

Accordingly, firm has applied for following products for consideration by the Registration Board.

Section	No. of Applied Products	No. of Molecule Applied
Oral Powder-I (General) Vet. Section	19	10
Oral Liquid-II (General) Vet. Section	13	10
Oral Powder Section-II Vet. (General)	18	10

	Oral Liquid Section-I Vet. (General)	23	10

Oral Powder Section-I Vet. (General)

(19 Products/ 10 Molecules)

343.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARCH NEO 72 WSP
	Composition	Each gram contains: Neomycin Sulphate…720mg
	Diary No. Date of R& I & fee	Dy.No 3271 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 123238030468)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Neokam-72 Powder of M/s. M.A. Kamil Farma (Pvt) Ltd., Plot Karachi. (Reg. No. 119740)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, foals, poultry
	Decision: Approved.	
344.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARCH NEO 100 WSP
	Composition	Each gram contains: Neomycin Sulphate…1000mg
	Diary No. Date of R& I & fee	Dy.No 3272 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 476208212)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Neokam-100 Powder of M/s. M.A.Kamil Farma (Pvt) Ltd., Plot Karachi. (Reg. No. 119739)
	GMP status	New DML

	Remarks of the Evaluator	**Target species:** Calves, foals, poultry
	Decision: Approved.	
345.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Gumbor WSP
	Composition	Each 100gram contains: Ammonium Chloride…70gm Methionine…10gm Sorbitol…5gm Vitamin A…150,000 IU Vitamin C…10gm
	Diary No. Date of R& I & fee	Dy.No 3273 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 0067132789)
	Pharmacological Group	Diuretic/Multivitamin
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Multivita Keyan Water Soluble Powder of M/s. Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111384)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
346.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch NOC 20 Oral Powder
	Composition	Each 1000gm contains: Oxytetracycline HCl…200gm Neomycin Sulphate…200gm Colistin Sulphate…240MIU
	Diary No. Date of R& I & fee	Dy.No 3275 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 745137592001)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Oxyno Plus Water Soluble Powder of M/s. Attabak Pharmaceuticals, Islamabad. (Reg. No.075682)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
347.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch NOC 8 Oral Powder
	Composition	Each gram contains: Oxytetracycline HCl…80mg Neomycin Sulphate…70mg Colistin Sulphate…4mg

	Diary No. Date of R& I & fee	Dy.No 3274 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 3705260381)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Pericycline Oral Powder of M/s. Ras Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 097918)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
348.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Mycoline Oral Powder
	Composition	Each 100gm contains: Oxytetracycline HCl…300mg Neomycin Sulphate…150mg Florfenicol…100mg
	Diary No. Date of R& I & fee	Dy.No 3278 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 60376339499)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Ofencin Oral Water Soluble Powder of M/s. D-Maarson Pharmaceuticals, Islamabad (Reg. No. 097869)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
349.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Mycoline Forte Oral Powder
	Composition	Each gram contains: Oxytetracycline HCl… 300mg Neomycin Sulphate… 150mg Florfenicol…100mg
	Diary No. Date of R& I & fee	Dy.No 3279 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 08627500556)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Neoxflor Oral Powder of M/s. Baariq Pharmaceuticals, Lahore. (Reg. No. 088638)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
350.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.

	Brand Name +Dosage Form + Strength	CRD Arch 40 Oral Powder
	Composition	Each gram contains: Doxycycline HCl…400mg Tylosin tartrate…200mg Colistin sulphate…0.5MIU Bromhexine HCl…10mg
	Diary No. Date of R& I & fee	Dy.No 3281 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 02927003278)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Broxtin 24-Powder of M/s. Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 088045)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
351.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	CRD Arch 20 Oral Powder
	Composition	Each gram contains: Doxycycline HCl…200mg Tylosin tartrate…100mg Colistin sulphate…0.5MIU Bromhexine HCl…5mg
	Diary No. Date of R& I & fee	Dy.No 3280 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 9126899702)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Div Doxy T 200 Water Soluble Powder of M/s. Divine Pharmaceuticals, Lahore. (Reg. No. 084948)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
352.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	CRD Arch 13 Oral Powder
	Composition	Each gram contains: Doxycycline HCl…130mg Tylosin tartrate…170mg Colistin sulphate…30mg Bromhexine HCl…5mg
	Diary No. Date of R& I & fee	Dy.No 3282 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 2077322498)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications

	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Anti-Bact Water Soluble Powder of M/s. Baariq Pharmaceuticals, Lahore (Reg. No. 087145)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
353.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Fortyl Forte Oral Powder
	Composition	Each gram contains: Fosfomycin Calcium…200mg Tylosin as Tartrate…100mg Fructose 1,6 Diphosphate…180mg Sodium Phosphate…150mg Magnesium Phosphate…100mg
	Diary No. Date of R& I & fee	Dy.No 3277 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 95534096212)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, and 1000gm; Decontrolled
	Me-too status	Fomyster Water Soluble Powder of M/s. Aamster Laboratories, Rawat, Islamabad. (Reg. No. 117263)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
354.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Dox 50% Water Soluble Powder
	Composition	Each gram contains: Doxycycline Hyclate…500mg
	Diary No. Date of R& I & fee	Dy.No 3283 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 09986896697)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Dox Plus 50% Water Soluble Powder of M/s. Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 082498)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Dogs, cats, horses
	Decision: Approved.	
355.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Dox 80% Water Soluble Powder
	Composition	Each gram contains: Doxycycline Hyclate…923.32mg (eq. to 800mg Doxycycline)

	Diary No. Date of R& I & fee	Dy.No 3284 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 65450572)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Doxyral 80% Water Soluble Powder of M/s. Orient Animal Health (Pvt.) Limited, Karachi (Reg. No. 082504)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Dogs, cats, horses
	Decision: Approved.	
356.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARCOL 48% Oral Powder
	Composition	Each gram contains: Colistin Sulphate…48,00,000IU
	Diary No. Date of R& I & fee	Dy.No 3285 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 083325991712)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Bio-Colistin Water Soluble Powder of M/s. Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 078291)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
357.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARCOL 60% Oral Powder
	Composition	Each gram contains: Colistin Sulphate…6,000,000IU
	Diary No. Date of R& I & fee	Dy.No 3286 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 49313818259)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Neflorex 60 Water Soluble Powder of M/s. Breeze Pharma (Pvt) Ltd., Islamabad. (Reg. No. 089855)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
358.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARCOL 55% Oral Powder
	Composition	Each Kg contains:

		Colistin Sulphate…550MIU
	Diary No. Date of R& I & fee	Dy.No 3287 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 49400542700)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Colimyxin G Water Soluble Powder of M/s. Divine Pharmaceuticals, Lahore. (Reg. No. 085155)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
359.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARCH CTC 20% Water Soluble Powder
	Composition	Each gram contains: Chlortetracycline HCl…200mg
	Diary No. Date of R& I & fee	Dy.No 3288 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 568549968790)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	CT More Water Soluble Powder of M/s. Moreno Iglisias Research Laboratories (Pvt) Ltd., Lahore. (Reg. No. 089851)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Dogs, cats, horses
	Decision: Approved.	
360.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARCH CTC 25% Water Soluble Powder
	Composition	Each gram contains: Chlortetracycline as HCl…250mg
	Diary No. Date of R& I & fee	Dy.No 3289 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 11589971533)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Meralin 250 Water Soluble Powder of M/s. Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 101462)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Dogs, cats, horses
	Decision: Approved.	
361.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.

	Brand Name +Dosage Form + Strength	Arch Fursa Oral Powder
	Composition	Each 1000gm contains: Furosemide…20gm Sodium Chloride…35gm Magnesium Sulphate…35gm Manganese Sulphate…1gm Calcium Carbonate…45gm Potassium Chloride…400mg
	Diary No. Date of R& I & fee	Dy.No 3290 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 52932804397)
	Pharmacological Group	Diuretic, electrolytes replenisher
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Neyphralyte Powder of M/s. Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071072)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
Oral Liquid-II (General) Vet. Section (13 Products/ 10 molecules)		
362.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Zen Drench
	Composition	Each 100ml contains: Oxyclozanide…3.0gm Levamisole HCl…1.50gm Sodium Selenite…0.167gm Cobalt Sulphate…0.05gm
	Diary No. Date of R& I & fee	Dy.No 3258 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 177210183)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Lefozan Plus Oral Drench of M/s. Prix Pharmaceutica (Pvt) Ltd.,Lahore (Reg. No. 075641)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, Calves, sheep, goats
	Decision: Approved.	
363.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Zen Forte Drench
	Composition	Each 100ml contains: Oxyclozanide…6.0gm Levamisole HCl…3.0gm Sodium Selenite…0.076gm Cobalt Sulphate…0.764gm

	Diary No. Date of R& I & fee	Dy.No 3259 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 14653468340)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	RK Levami 6/3/0.764/0.076 Drench of M/s. Athan Pharmaceuticals, Hattar (Reg. No. 115035)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, Calves, sheep, goats
	Decision: Approved.	
364.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Ben 2.5% Drench
	Composition	Each 100ml contains: Albendazole…2.5gm Sodium Selenite…0.035gm Cobalt Sulphate…0.075gm
	Diary No. Date of R& I & fee	Dy.No 3260 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 4907650722)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Nobialba Suspension of M/s. Noble Pharma, Mirpur Azad Kashmir. (Reg. No. 062124)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, sheep, goats
	Decision: Approved.	
365.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Ben 12.5% Drench
	Composition	Each 100ml contains: Albendazole…12.5gm Sodium Selenite…0.035gm Cobalt Sulphate…0.382gm
	Diary No. Date of R& I & fee	Dy.No 3261 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 382357397)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Albadec Super Oral Liquid of M/s. Biogen Pharma, Chakbele Road, Rawat. (Reg. No. 048238)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, sheep, goats
	Decision: Approved.	

366.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Ox 2.265% Drench
	Composition	Each 100ml contains: Oxfendazole…2.265gm Sodium Selenite…0.030gm Cobalt Chloride…0.075gm
	Diary No. Date of R& I & fee	Dy.No 3262 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 7016671328)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Fenzole CS Suspension of M/s. Attabak Pharmaceutical Islamabad (Reg. No. 058901)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats, horses
	Decision: Approved.	
367.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Clofen Drench
	Composition	Each ml contains: Oxyclozanide…62.5mg Oxfendazole…22.65mg Sodium Selenite…0.5mg Cobalt Sulphate…1.67mg
	Diary No. Date of R& I & fee	Dy.No 3263 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 985108839880)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Finisher Drench of M/s. Mylab (Pvt) Ltd. Bahawalpur (Reg. No. 073901)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats, horses
	Decision: Approved.	
368.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Skol oral suspension
	Composition	Each ml contains: Sulphadiazine…35.50mg Sulphadimidine…28.40mg Neomycin Sulphate…1.80mg Hyoscine N Butylbromide…0.04mg Pectin…7.10mg Kaolin…103.30mg Vitamin B1…0.15mg Vitamin B2…0.22mg

	Diary No. Date of R& I & fee	Dy.No 3264 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 4921886972)
	Pharmacological Group	Antibiotics, vitamins, antidiarrheal
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Scour-X Oral Suspension of M/s. Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No.029661)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, camelids, sheep, goats, horses
	Decision: Approved.	
369.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Leva 1.5% Drench
	Composition	Each 100ml contains: Levamisole HCl…1.5gm
	Diary No. Date of R& I & fee	Dy.No 3265 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 89231382)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Levawan Oral Liquid of M/s. Prix Pharmaceutica (Pvt) Ltd., Lahore (Reg. No.075642)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats
	Decision: Approved.	
370.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Clazole 5% Suspension
	Composition	Each 100ml contains: Triclabendazole…5% Levamisole HCl…3.75% Sodium Selenite…0.035% Cobalt Chloride…0.075%
	Diary No. Date of R& I & fee	Dy.No 3266 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 0987703967)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Trizen 8.75 Oral Liquid of M/s. Elegance Pharmaceuticals, Rawalpindi (Reg. No. 078284)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats
	Decision: Approved.	
371.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.

	Brand Name +Dosage Form + Strength	Clazole 12% Suspension
	Composition	Each ml contains: Triclabendazole…120mg Levamisole HCl…75mg Sodium Selenite…0.35mg Cobalt Chloride…0.75mg
	Diary No. Date of R& I & fee	Dy.No 3267 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 1025806543)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Clovetz SC Oral Liquid of M/s. Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No.089831)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats
	Decision: Approved.	
372.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Mecben Drench
	Composition	Each 100ml contains: Triclabendazole…12gm Ivermectin…0.2gm Albendazole…10gm
	Diary No. Date of R& I & fee	Dy.No 3268 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 731394881738)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Thunder Drench of M/s. Star Laboratories (Pvt) Ltd, Lahore (Reg. No. 058941)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats
	Decision: Approved.	
373.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Clo Suspension
	Composition	Each 100ml contains: Oxyclozanide…3.4%
	Diary No. Date of R& I & fee	Dy.No 3269 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 895045970)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Clozak Suspension of M/s. Attabak Pharmaceuticals Islamabad. (Reg. No. 053911)

	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats
	Decision: Approved.	
374.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Oxal oral suspension
	Composition	Each litre contains: Oxfendazole…22.65gm Triclabendazole…85gm
	Diary No. Date of R& I & fee	Dy.No 3270 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 7547035418)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Vorcid Suspension of M/s. Breeze Pharma (Pvt.) Ltd., Islamabad. (Reg. No. 063563)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats
	Decision: Approved.	
	Oral Powder Section-II Vet. (General) **(18 Products/ 10 Molecules)**	
375.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARCH LEV 15% Powder
	Composition	Each 100gm contains: Levamisole HCl…15gm
	Diary No. Date of R& I & fee	Dy.No 3291 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 591761281)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Lemisole 15% Water Soluble Powder of M/s. Attabak Pharmaceutical Islamabad (Reg. No. 058883)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats, poultry ➢ Official monograph of the applied formulation is **not available in BP.** Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved with as per innovator's specifications. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.	
376.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARCH LEV 20% Powder

	Composition	Each 100gm contains: Levamisole HCl…20gm
	Diary No. Date of R& I & fee	Dy.No 3292 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 8044901952)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Levabak Water Soluble Powder of M/s. Attabak Pharmaceutical Islamabad (Reg. No. 053902)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats, poultry ➢ Official monograph of the applied formulation is **not available in BP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved with as per innovator's specifications. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.	
377.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARCH LEV 50% Powder
	Composition	Each 100gm contains: Levamisole HCl…50gm
	Diary No. Date of R& I & fee	Dy.No 3293 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 0524856725)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Levafic-500 oral powder of M/s. Biorific Pharma, Islamabad. (Reg. No. 118666)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats, poultry ➢ Official monograph of the applied formulation is **not available in BP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved with as per innovator's specifications. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.	
378.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Archoban Powder
	Composition	Each gram contains: Neomycin Sulphate…33.33mg Streptomycin Sulphate…33.33mg Sulphaguanidine…333.33mg Pectin…33.33mg Bismuth Subnitrate…166.66mg Vitamin A Acetate…2.291mg Kaolin…333.33mg

	Diary No. Date of R& I & fee	Dy.No 3294 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 7689159746)
	Pharmacological Group	Antibacterial, vitamin, anti-diarrheal
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Diarrolex water soluble powder of M/s Wimits Pharmaceuticals, Lahore. (Reg. No. 080151)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats, poultry
	Decision: Approved.	
379.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Archoban Forte Powder
	Composition	Each 12gram contains: Neomycin Sulphate…400mg Streptomycin Sulphate…400mg Sulphaguanidine…4000mg Pectin…400mg Bismuth Subnitrate…2000mg Vitamin A Acetate…80000 I.U. Kaolin…4000gm
	Diary No. Date of R& I & fee	Dy.No 3295 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 685297546)
	Pharmacological Group	Antibacterial, vitamin, anti-diarrheal
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Diarroban Powder of M/s Star Labs Lahore (Reg. No. 026438)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats, poultry
	Decision: Approved.	
380.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Gasiton Powder
	Composition	Each 1000gm contains: Propionic Acid Calcium…250gm Propionic Acid Sodium…400gm Acetanilide…150gm Magnesium Oxide…125gm Iron II Sulphate…400mg Zinc Sulphate…100mg Magnesium Sulphate…200mg Copper Sulphate…450mg Cobalt Sulphate…400mg Sodium Molybdate…100mg Sodium Chloride…20gm
	Diary No. Date of R& I & fee	Dy.No 3296 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 7241496642)

	Pharmacological Group	Nutritional powder digestive supplement
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Anigest Powder of M/s Mylab (Pvt) Ltd. Bahawalpur (Reg. No. 073906)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats, poultry
	Decision: Approved.	
381.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Linco 11 Pre Mix
	Composition	Each gram contains: Lincomycin HCl…11mg
	Diary No. Date of R& I & fee	Dy.No 3297 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 2091561585)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Linco Grow 11 Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No.118651)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Dogs, cats **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Approved with change of brand name. Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
382.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Linco 44 Pre Mix
	Composition	Each gram contains: Lincomycin HCl…44mg
	Diary No. Date of R& I & fee	Dy.No 3298 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 689592262381)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Linco Grow 44 Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 118650)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Dogs, cats **Shortcomings:**

		Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Approved with change of brand name. Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
383.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Stone Fon 96 Powder
	Composition	Each gram contains: Trichlorfon…960mg
	Diary No. Date of R& I & fee	Dy.No 3299 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 7187069986)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Ectozone-96 Powder of M/s Qas International, Kamoki, District Gujranwala. (Reg. No. 117073)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, sheep, goats, poultry
	Decision: Approved.	
384.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Stone Fon 98 Powder
	Composition	Each gram contains: Trichlorfon…980mg
	Diary No. Date of R& I & fee	Dy.No 3300 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 56842725417)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Ectozone-98 Powder of M/s Qas International, Kamoki, District Gujranwala. (Reg. No. 117074)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, sheep, goats, poultry
	Decision: Approved.	
385.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Colin Powder
	Composition	Each gram contains: Lincomycin HCl…100mg Colistin Sulphate…800000IU
	Diary No. Date of R& I & fee	Dy.No 3301 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 297584730205)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications

	Pack size & Demanded	100gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Col-Link Powder of M/s Farm Aid Group, Haripur (Reg. No.118584)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
386.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ampro Arch 20% Powder
	Composition	Each gram contains: Amprolium HCl…200mg
	Diary No. Date of R& I & fee	Dy.No 3304 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 65168735)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	100gm, 230gm, 500gm, 1000gm, 2500gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Acmepro-20 Water Soluble Powder of M/s Acme Pharmaceuticals, Rawat, Islamabad (Reg. No. 118474)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
387.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ampro Arch 50% Powder
	Composition	Each gram contains: Amprolium HCl…500mg
	Diary No. Date of R& I & fee	Dy.No 3303 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 1190445513)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	100gm, 230gm, 500gm, 1000gm, 2500gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Prolin Powder of M/s Inshal Pharmaceutical Industries, Rawat, Islamabad. (Reg. No. 118447)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
388.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ampro Arch 90% Powder
	Composition	Each gram contains: Amprolium HCl…900mg
	Diary No. Date of R& I & fee	Dy.No 3302 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 2691914089)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5

	Finished product Specification	USP Specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Amprohawk-90 Oral Powder of M/s Hawk Bio Pharma (Pvt) Ltd., Rawat, Islamabad. (Reg. No. 118432)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
389.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Strep Dox 20 Powder
	Composition	Each gram contains: Doxycycline HCl…200mg Tylosin Tartrate…100mg Dihydrostreptomycin…20mg Bromhexine HCl…5mg
	Diary No. Date of R& I & fee	Dy.No 3305 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 5255551920)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, and 25000gm; Decontrolled
	Me-too status	Doxylo-S Water Soluble Powder of M/s Attabak Pharmaceuticals, Islamabad (Reg. No. 075695)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
390.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Strep Dox 40 Powder
	Composition	Each gram contains: Doxycycline HCl…200mg Tylosin Tartrate…100mg Dihydrostreptomycin…40mg Bromhexine HCl…5mg
	Diary No. Date of R& I & fee	Dy.No 3306 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 629094274)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, and 25000gm; Decontrolled
	Me-too status	Tylobrom-S Powder of M/s Attabak Pharmaceuticals, Islamabad (Reg. No.075698)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
391.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.

	Brand Name +Dosage Form + Strength	Arch Med W/S Powder
	Composition	Each 100gm contains: Methenamine…95gm Vitamin B1…800mg Vitamin B2…920mg Vitamin K3…200mg
	Diary No. Date of R& I & fee	Dy.No 3307 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 14287669561)
	Pharmacological Group	Multivitamin & Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, and 25000gm; Decontrolled
	Me-too status	Renofic Oral Powder of M/s Biorific Pharma, Islamabad (Reg. No. 117286)
	GMP status	New DML
	Remarks of the Evaluator	**Shortcomings:** ➢ clarification regarding solubility of instant formulation
	Decision: Deferred for clarification regarding solubility of instant formulation.	
392.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Spiro Spec Powder
	Composition	Each 100gm contains: Lincomycin HCl…5gm Spectinomycin HCl…7.5gm Spiramycin Adipate…2.5gm Bromhexine HCl…0.5gm
	Diary No. Date of R& I & fee	Dy.No 3308 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 60385158188)
	Pharmacological Group	Antibacterial, bronchodilator
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100gm, 200gm, 500gm, 1000gm, 5000gm, 10000gm, and 25000gm; Decontrolled
	Me-too status	Spiralinc-B Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 079716)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry, livestock
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
Oral Liquid Section-I Vet. (General) **(23 Products/ 10 Molecules)**		
393.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Til Liquid
	Composition	Each 100ml contains:

		Tilmicosin Phosphate…25gm
	Diary No. Date of R& I & fee	Dy.No 3235 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 2444535711)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Tilco Mal Liquid of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118612)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, broilers, turkeys **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Approved. Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
394.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Fen 20% Liquid
	Composition	Each 100ml contains: Florfenicol…20gm
	Diary No. Date of R& I & fee	Dy.No 3236 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 04020152818)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Florel Oral Liquid of M/s Biorific Pharma, Islamabad. (Reg. No.118661)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:**

		Poultry
	Decision: Approved.	
395.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Fen 23% Liquid
	Composition	Each 100ml contains: Florfenicol…23gm
	Diary No. Date of R& I & fee	Dy.No 3237 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 22122657)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Makflor-23 Oral Liquid of M/s M.A. Kamil Farma (Pvt) Ltd., Karachi. (Reg. No. 119748)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
396.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Fen 25% Liquid
	Composition	Each ml contains: Florfenicol…250mg
	Diary No. Date of R& I & fee	Dy.No 3238 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 93865982734)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Poul Flor-25 Oral Solution of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118545)

	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
397.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Rotin 10% Liquid
	Composition	Each 100ml contains: Florfenicol…10gm Colistin Sulphate…50MIU
	Diary No. Date of R& I & fee	Dy.No 3239 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 802311268)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Feniczone-10 Oral Liquid of M/s Qas International, Kamoki, District Gujranwala (Reg. No. 117053)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
398.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Rotin 23% Liquid
	Composition	Each 1000ml contains: Florfenicol…230gm Colistin Sulphate…500MIU
	Diary No. Date of R& I & fee	Dy.No 3240 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 821189170476)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5

	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Z-Florcol oral liquid of M/s Zoic International, Lahore. (Reg. No. 080940)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
399.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Rotin 25% Liquid
	Composition	Each 100ml contains: Florfenicol…25gm Colistin Sulphate…50MIU
	Diary No. Date of R& I & fee	Dy.No 3241 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 2743686998)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Flocol Liquid of M/s D-Maarson pharmaceuticals, Rawat, Islamabad (Reg. No. 074082)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
400.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Diatrim Oral Liquid
	Composition	Each ml contains: Trimethoprim…80mg

		Sulphadiazine…400mg
	Diary No. Date of R& I & fee	Dy.No 3242 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 65966950031)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Timobar Suspension of M/s Baariq Pharmaceuticals, Lahore (Reg. No. 079817)
	GMP status	New DML
	Remarks of the Evaluator	**Shortcomings:** Official monograph of the applied formulation is **not available in BP.** Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.	
401.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Brom 1% Oral Liquid
	Composition	Each ml contains: Bromhexine HCl…10mg
	Diary No. Date of R& I & fee	Dy.No 3243 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 18484650482)
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Bronchi Poul-1% Oral Liquid of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118533)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	

402.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Brom 5% Oral Liquid
	Composition	Each ml contains: Bromhexine HCl…50mg
	Diary No. Date of R& I & fee	Dy.No 3245 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 76058488263)
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Bronchi Poul-5% Oral Liquid of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118534)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
403.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Brom 2% Oral Liquid
	Composition	Each ml contains: Bromhexine HCl…20mg
	Diary No. Date of R& I & fee	Dy.No 3244 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 381894564)
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Cof Rold 2% Oral Liquid of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 114911)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	

404.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Enstin 10 Liquid
	Composition	Each ml contains: Enrofloxacin…100mg Colistin Sulphate…0.48 MIU
	Diary No. Date of R& I & fee	Dy.No 3246 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 041524552293)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Quino Poul-58-Oral Liquid of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118542)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
405.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Enstin 20 Liquid
	Composition	Each ml contains: Enrofloxacin…200mg Colistin Sulphate…30mg
	Diary No. Date of R& I & fee	Dy.No 3247 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 70581125697)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Eflin-UA 20% oral liquid of M/s Vetec Laboratories, Rawat, Rawalpindi. (Reg. No.099307)
	GMP status	New DML

	Remarks of the Evaluator	
	Decision: Approved.	
406.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Enstin 25 Liquid
	Composition	Each ml contains: Enrofloxacin…250mg Colistin Sulphate…0.050 MIU
	Diary No. Date of R& I & fee	Dy.No 3248 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 1343837313)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Eflin-DA 25% oral liquid of M/s Vetec Laboratories, Rawat, Rawalpindi. (Reg. No. 099306)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
407.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Roxcin 10 Liquid
	Composition	Each 100ml contains: Enrofloxacin…10gm
	Diary No. Date of R& I & fee	Dy.No 3249 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 120701008648)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Enster 10 Oral Liquid of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No. 101500)

	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
408.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Roxcin 20 Liquid
	Composition	Each 100ml contains: Enrofloxacin…20gm
	Diary No. Date of R& I & fee	Dy.No 3250 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 47147790865)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Enster 20 Oral Liquid of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No. 101501)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
409.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Roxcin 25 Liquid
	Composition	Each 100ml contains: Enrofloxacin…25gm
	Diary No. Date of R& I & fee	Dy.No 3251 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 6952362663)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Enrozone-25 Oral Liquid of M/s QAS International,

		Kamoki, District Gujranwala (Reg. No. 117067)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
410.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Liver Oral Liquid
	Composition	Each ml contains: L-Carnitine …50mg Betaine…20mg Choline Chloride…100mg Inositol…7mg Magnesium Sulphate…10mg Sorbitol…200mg
	Diary No. Date of R& I & fee	Dy.No 3252 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 85376328962)
	Pharmacological Group	Amino acids, Laxative
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Makliv Solution of M/s M.A. Kamil Farma (Pvt) Ltd., Karachi (Reg. No. 119744)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry, cow, cattle, horse, camel, goat, fish
	Decision: Approved.	
411.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARCH BM 30 Liquid
	Composition	Each ml contains: Bromhexine HCl…10mg Menthol…20mg

	Diary No. Date of R& I & fee	Dy.No 3253 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 78824261163)
	Pharmacological Group	Mucolytic, Anesthetic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Bronchoment-10 Oral Liquid of M/s M.A. Kamil Farma (Pvt) Ltd., Karachi (Reg. No. 119753)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
412.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARCH BM 60 Liquid
	Composition	Each ml contains: Bromhexine HCl…20mg Menthol…40mg
	Diary No. Date of R& I & fee	Dy.No 3254 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 354848848763)
	Pharmacological Group	Mucolytic, Anesthetic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Bronchoment-20 Oral Liquid of M/s M.A. Kamil Farma (Pvt) Ltd., Karachi (Reg. No. 119754)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
413.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARCH BM 90 Liquid
	Composition	Each ml contains:

		Bromhexine HCl…50mg Menthol…40mg
	Diary No. Date of R& I & fee	Dy.No 3255 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 575655484606)
	Pharmacological Group	Mucolytic, Anesthetic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Hexthol Liquid of M/s Nawal Pharmaceuticals, Taxila, Rawalpindi (Reg. No. 097984)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
414.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	ARCH Clozol 2.5 Suspension
	Composition	Each ml contains: Albendazole…25mg Closantel…5mg
	Diary No. Date of R& I & fee	Dy.No 3256 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 45976834048)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Benda Santel 2.5% Oral Suspension of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 111361)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, sheep, goats
	Decision: Approved.	
415.	Name and address of manufacturer / Applicant	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK.

	Brand Name +Dosage Form + Strength	ARCH Clozol 10 Suspension
	Composition	Each ml contains: Albendazole…100mg Closantel…20mg
	Diary No. Date of R& I & fee	Dy.No 3257 dated 20-02-2024 Rs 30,000/- dated 19-02-2024 (Slip No. 281378564428)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Benda Santel 10% Oral Suspension of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 111362)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, sheep, goats
	Decision: Approved.	

II. M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.

CLB in its 294th meeting held on 27th December, 2023 has considered and approved the grant of DML by way of formulation with following section(s):

1. Oral Liquid Section (General) Vet.

Accordingly, firm has applied for following products for consideration by the Registration Board.

Section	No. of Applied Products	No. of Molecule Applied
Oral Liquid Section (General) Vet.	17	10

Oral Liquid Section (General) Vet.
(17 Products/ 10 Molecules)

416.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Soc-Nix Plus Drench
	Composition	Each ml contains: Oxyclozanide.....94mg Oxfendazole.....34mg Cobalt Sulphate.....3.82mg Sodium Selenite.....0.50mg
	Tracking ID, date & fee	RGX-5PV-U7GS dated 08-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 1092814964)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications

	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Buster Forte Drench of M/s. Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119726)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Livestock, poultry
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
417.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Soc-Nix Super Drench
	Composition	Each ml contains: Oxyclozanide.....62.50mg Oxfendazole.....25mg Cobalt Sulphate.....2mg Sodium Selenite.....0.50mg
	Tracking ID, date & fee	XMG-RY1-T4TQ dated 08-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 63924412487)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Nidozole Drench of M/s. Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109084)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Livestock, poultry **Shortcomings:** Initially, the applied formulation contains Oxyclozanide .....62.50**gm/ml,** the firm has now revised formulation as per following label claim: **Each ml contains:** **Oxyclozanide.....62.50mg** **Oxfendazole.....25mg** **Cobalt Sulphate.....2mg** **Sodium Selenite.....0.50mg** The firm has **NOT** submitted fee for revision of formulation.
	Decision: Approved. Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
418.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Los-Nix DS Suspension
	Composition	Each 100ml contains: Oxyclozanide.....30mg Levamisole HCl.....15mg Cobalt Chloride.....3.80mg Sodium Selenite.....3.5mg
	Tracking ID, date & fee	7UJ-PML-UEQS dated 08-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 1758229841)

	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Roldzen DS Oral Suspension of M/s. Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109064)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Livestock, poultry
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
419.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Los-Nix SC Suspension
	Composition	Each 100ml contains: Oxyclozanide.....6gm Levamisole HCl.....3gm Cobalt Chloride.....0.15gm Sodium Selenite.....0.07gm
	Tracking ID, date & fee	QHW-9ST-A7Y8 dated 09-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 889189122678)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Roldzen Super Suspension of M/s. Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109067)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Livestock, poultry
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
420.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Hpk-Nix Suspension
	Composition	Each ml contains: Sulphadiazine.....35.5mg Sulphadimidine.....28.4mg Neomycin Sulphate.....1.8mg Hyoscine Methylbromide.....0.04mg Pectin.....7.1mg Kaolin.....103.3mg Vitamin B1.....0.15mg Vitamin B2.....0.22mg Vitamin B6.....0.15mg Vitamin K3.....4mg
	Tracking ID, date & fee	QTB-BV4-L22N dated 09-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 4021651726)
	Pharmacological Group	Antibiotic, Vitamin, mineral
	Type of Form	Form 5

	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Rexin Oral Suspension of M/s. Evergreen Pharmaceuticals, Lahore. (Reg. No. 118400)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
421.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	MC-Nix Suspension
	Composition	Each 5ml contains: Closantel.....250mg Mebendazole.....375mg
	Tracking ID, date & fee	Z67-XDY-P918 dated 10-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 591044235377)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Clomeb Super Oral Drench of M/s. Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 041284)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
422.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Tl-Nix Forte Suspension
	Composition	Each ml contains: Triclabendazole.....50mg Levamisole HCl.....37.5mg Cobalt Sulphate.....1.67mg Sodium Selenite.....0.35mg
	Tracking ID, date & fee	STW-Y4G-Z6XZ dated 11-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 65556117119)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Trizak Suspension of M/s. Zakfas Pharmaceuticals Pvt Ltd., Multan. (Reg. No. 118561)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Livestock, poultry
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
423.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Ocs-Nix Suspension
	Composition	Each 100ml contains: Oxfendazole.....2.265gm

		Cobalt Sulphate.....0.167gm Sodium Selenite.....0.05gm
	Tracking ID, date & fee	YHH-PU2-71P1 dated 11-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 53086520912)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Wantox Plus Suspension of M/s. Vety-Care Pharmaceuticals (Pvt) Ltd., Islamabad. (Reg. No. 028517)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Livestock, poultry
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
424.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	E.C.NIX 10/50 Oral Liquid
	Composition	Each 100ml contains: Enrofloxacin.....10gm Colistin Sulphate.....50MIU
	Tracking ID, date & fee	W9G-RQ6-9X77 dated 11-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 3568593050)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Enc-Zone 10 Oral Liquid of M/s. QAS International, Kamoki, District Gujranwala. (Reg. No. 117054)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Livestock, poultry
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
425.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	E.C.NIX 20/3 Oral Liquid
	Composition	Each ml contains: Enrofloxacin.....20% Colistin Sulphate.....3%
	Tracking ID, date & fee	QUN-R7T-ATVP dated 11-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 70800006)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Acmecoliflox 20/3 Oral Liquid of M/s. Acme Pharmaceuticals, Rawat, Islamabad. (Reg. No. 117019)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Livestock, poultry

	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
426.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	E.C.NIX 20/50 Oral Liquid
	Composition	Each 100ml contains: Enrofloxacin.....20gm Colistin Sulphate.....50MIU
	Tracking ID, date & fee	RJN-Z72-BZD7 dated 11-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 7900886246)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Enrokam C-20 Oral Solution of M/s. M.A. Kamil Farma (Pvt) Ltd., Karachi. (Reg. No. 119751)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Livestock, poultry
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
427.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	E.C.NIX 25/5 Oral Liquid
	Composition	Each 100ml contains: Enrofloxacin.....5gm Colistin Sulphate.....25MIU
	Tracking ID, date & fee	USY-SU3-VYBU dated 12-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 69071874135)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Enro Plus of M/s. Leads Pharma (Pvt) Ltd Islamabad. (Reg. No. 057045)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Livestock, poultry
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
428.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Essitin Forte Oral Liquid
	Composition	Each ml contains: Enrofloxacin.....75mg Sulphamethoxypridazine.....50mg Sulphamethazine.....50mg Trimethoprim.....25mg
	Tracking ID, date & fee	15A-E5E-HBQQ dated 12-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 03928157)
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Sulphacina Oral Liquid of M/s. Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 074786)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Livestock, poultry
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
429.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Essitin Plus Oral Liquid
	Composition	Each ml contains: Enrofloxacin.....75mg Sulphamethoxypridazine.....75mg Sulphamethazine.....50mg Trimethoprim.....25mg
	Tracking ID, date & fee	EAY-TNQ-UE9U dated 12-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 16241534402)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Entri SS Oral Liquid of M/s. Suave Pharmaceuticals Pvt. Ltd., Khurianwala, Faisalabad (Reg. No. 117129)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Livestock, poultry
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
430.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Flornix-10 Oral Liquid
	Composition	Each ml contains: Florfenicol.....100mg
	Tracking ID, date & fee	AAW-2R8-RH4J dated 12-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 20151804271)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Poul Flor-10 Oral Solution of M/s. Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118543)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
431.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.

	Brand Name +Dosage Form + Strength	Flornix-23 Oral Liquid
	Composition	Each ml contains: Florfenicol.....230mg
	Tracking ID, date & fee	978-JT9-233Z dated 12-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 2465052349)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Poul Flor-23 Oral Solution of M/s. Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No.118544)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
432.	Name and address of manufacturer / Applicant	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Til Nix Oral Liquid
	Composition	Each ml contains: Tilmicosin as Phosphate.....250mg
	Tracking ID, date & fee	GZJ-L1G-NT35 dated 12-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 18283887057)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Tilco Mal Liquid of M/s. Mallard Pharmaceuticals (Pvt) Ltd.,23 Multan (Reg. No.118612)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle
	Decision: Approved.	

Case no.02 Registration applications of New Section (Veterinary)

a. New Cases

I. M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore.

CLB in its 294th meeting held on 27th December, 2023 has considered and approved the grant of following two additional sections:

1. Oral Liquid (Veterinary) Section (New)
2. Oral Powder (Veterinary) Section (New)

Accordingly, firm has applied for following products for consideration by the Registration Board.

Section	No. of Applied Products	No. of Molecule Applied

	Oral Liquid (Veterinary) Section (New)	10	10
	Oral Powder (Veterinary) Section (New)	10	10

Oral Liquid (Veterinary) Section (New)

(10 Products/ 10 Molecules)

433.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR EC Med Super oral solution
	Composition	Each ml contains: Enrofloxacin..... 200mg Colistin Sulphate 0.5MIU
	Tracking Id, date & fee	3L4-QE6-1GQA dated 02-03-2024 Rs 30,000/- dated 02-03-2024 (Slip No. 29590487418)
	Pharmacological Group	Antimicrobial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	1000ml and 5000ml; Decontrolled
	Me-too status	Quino Poul-70-Oral Liquid of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118540)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Calves, poultry **Shortcomings:** Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
434.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Floramed Plus oral solution
	Composition	Each 100ml contains: Florfenicol..... 23gm

		Colistin Sulphate ..... 50 MIU
	Tracking Id, date & fee	1JZ-2QN-WRBG dated 02-03-2024 Rs 30,000/- dated 02-03-2024 (Slip No. 67931188385)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	1000ml and 5000ml; Decontrolled
	Me-too status	Feniczone-23 Oral Liquid of M/s QAS International, Kamoki, District Gujranwala (Reg. No. 117051)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock, poultry **Shortcomings:** Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
435.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR Floramed-23 oral solution
	Composition	Each ml contains: Florfenicol..... 230mg
	Tracking Id, date & fee	2T2-D38-G86W dated 02-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 950750297800)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	1000ml and 5000ml; Decontrolled
	Me-too status	Floribal Liquid of M/s Wimits Pharmaceuticals, Lahore (Reg. No. 078331)
	GMP status	New Section

	Remarks of the Evaluator	**Target species:** Livestock, poultry **Shortcomings:** Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
436.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR Talcomed oral solution
	Composition	Each ml contains: Tilmicosin as Phosphate..... 250mg
	Tracking Id, date & fee	333-UQ3-QR31 dated 02-03-2024 Rs 30,000/- dated 28-02-2024 (Slip No. 358710403489)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	1000ml and 5000ml; Decontrolled
	Me-too status	Tilco Mal Liquid of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118612)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** calves, chickens, turkeys **Shortcomings:** Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
437.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	BROMED-5 oral solution

	Composition	Each ml contains: Bromhexine HCl..... 50mg
	Tracking Id, date & fee	69N-8GD-ETML dated 03-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 23872871)
	Pharmacological Group	Mucolytic & Expectorant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	1000ml and 5000ml; Decontrolled
	Me-too status	Bromokam-5 Oral Liquid of M/s M.A.Kamil Farma (Pvt) Ltd., Karachi (Reg. No.119752)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Poultry **Shortcomings:** Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
438.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	E Med-10 oral solution
	Composition	Each ml contains: Enrofloxacin..... 100mg
	Tracking Id, date & fee	9P6-YZP-2R9P dated 03-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 7894877399)
	Pharmacological Group	Antimicrobial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	1000ml and 5000ml; Decontrolled
	Me-too status	Floxa-10 Solution of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 088856)
	GMP status	New Section
	Remarks of the Evaluator	**Shortcomings:**

		Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
439.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR MINT MED oral solution
	Composition	Each ml contains: Bromhexine HCl..... 20 mg Menthol..... 40 mg
	Tracking Id, date & fee	GAM-UD2-U3VP dated 02-03-2024 Rs 30,000/- dated 28-02-2024 (Slip No. 1689445652)
	Pharmacological Group	Mucolytic & Expectorant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	1000ml and 5000ml; Decontrolled
	Me-too status	Minto Mall Liquid of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118611)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Poultry **Shortcomings:** Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
440.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR ENROMED.SS oral solution
	Composition	Each ml contains: Enrofloxacin..... 75mg Sulfamethoxypyridazine..... 75mg

		Sulfamethazine..... 50mg Trimethoprim..... 25mg
	Tracking Id, date & fee	TA3-B2Y-L3ZQ dated 02-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 44834461047)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	1000ml and 5000ml; Decontrolled
	Me-too status	Cinariq Oral Liquid of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 117139)
	GMP status	New Section
	Remarks of the Evaluator	**Shortcomings:** Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
441.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR Toltamed 2.5 oral solution
	Composition	Each 100ml contains: Toltrazuril ..... 2.5 gm
	Tracking Id, date & fee	UYW-62T-BV6A dated 03-03-2024 Rs 30,000/- dated 28-02-2024 (Slip No. 0153897931)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	100ml, 500ml, and 1000ml; Decontrolled
	Me-too status	Mili Toltrazuril Oral Liquid of M/s Mili Vet Pharmaceuticals (Pvt) Ltd Raiwind, Lahore (Reg. No. 112196)
	GMP status	New Section
	Remarks of the Evaluator	**Shortcomings:**

		Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
442.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR TRIMED oral suspension
	Composition	Each ml contains: Trimethoprim ..... 80 mg Sulphadiazine ..... 400 mg
	Tracking Id, date & fee	WQ4-LG5-92G4 dated 03-03-2024 Rs 30,000/- dated 28-02-2024 (Slip No. 73055084)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	100ml, 500ml, 1000ml and 5000ml; Decontrolled
	Me-too status	Triph oral suspension of M/s Poulvet Pharmaceuticals (Pvt) Ltd Multan (Reg. No. 118547)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Poultry, cattle, cows, mares **Shortcomings:** Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Deferred for clarification regarding intended use in specifically cows and mares only.	
Oral Powder (Veterinary) Section (New) **(10 Products/ 10 Molecules)**		
443.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Medoxi-TBC oral powder
	Composition	Each gram contains:

		Doxycycline Hyclate ..... 200 mg Colistin Sulphate ..... 25 mg Tylosin Tartrate ..... 100 mg Bromhexine HCl ..... 5 mg
	Tracking Id, date & fee	XDM-ZES-E692 dated 04-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 75931853)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	500gm, 1000gm and 5000gm; Decontrolled
	Me-too status	D-Dox 20 Powder of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 118471)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Poultry, livestock **Shortcomings:** Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product and finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
444.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR Paramed C Oral Powder
	Composition	Each 100gram contains: **Paracetamol**..... 20gm **Vitamin C**..... 5gm Potassium Carbonate..... 12.5gm Sodium bicarbonate..... 12.5gm Vitamin E..... 12.5gm
	Tracking Id, date & fee	PPT-XZ2-7V28 dated 04-03-2024 Rs 30,000/- dated 28-02-2024 (Slip No. 18074311812)

	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	500gm, 1000gm and 5000gm; Decontrolled
	Me-too status	Parold C Water Soluble Powder of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109123)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Poultry **Shortcomings:** Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
445.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR Nfcole oral powder
	Composition	Each gram contains: Neomycin Sulphate..... 150mg Florfenicol..... 100mg Oxytetracycline HCl 300mg
	Tracking Id, date & fee	W1B-1XT-9942 dated 04-03-2024 Rs 30,000/- dated 28-02-2024 (Slip No. 38765319669)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	500gm, 1000gm, 5000gm and 10000gm; Decontrolled
	Me-too status	Floxy-N Mak Water Soluble Powder of M/s M.A.Kamil Farma (Pvt) Ltd., Karachi (Reg. No. 119741)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Poultry, calves **Shortcomings:**

		Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
446.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR Neomed-72 Oral Powder
	Composition	Each gram contains: Neomycin Sulphate 720mg
	Tracking Id, date & fee	3RT-7R4-XLRA dated 04-03-2024 Rs 30,000/- dated 28-02-2024 (Slip No. 44739336989)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	500gm, 1000gm, and 5000gm; Decontrolled
	Me-too status	Neom-72 Water Soluble Powder of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118506)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Poultry, calves, sheep, goats **Shortcomings:** Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
447.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR Medncol-19 Oral Powder
	Composition	Each gram contains: Colistin Sulphate..... 4mg Chlortetracycline HCl..... 80mg Neomycin Sulphate..... 70mg

	Tracking Id, date & fee	JS7-77A-1QSR dated 04-03-2024 Rs 30,000/- dated 28-02-2024 (Slip No. 564955087682)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	500gm, 1000gm, 5000gm and 10000gm; Decontrolled
	Me-too status	Poul CNC Water Soluble Powder of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118517)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Poultry **Shortcomings:** Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
448.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR Medlinco 4.4 Oral Powder
	Composition	Each 100gm contains: Lincomycin (as HCl) 4.4gm
	Tracking Id, date & fee	7ZQ-538-XAG3 dated 03-03-2024 Rs 30,000/- dated 28-02-2024 (Slip No. 33278502774)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Linco Grow 44 Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 118650)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Poultry **Shortcomings:**

		Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
449.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR Furosmed Oral Powder
	Composition	Each Kg contains: Furosemide.....20gm Sodium Chloride .....35gm Potassium Chloride.....400mg Magnesium Chloride.....35gm Calcium Carbonate.....45gm Manganese Sulphate ..... 1 gm
	Tracking Id, date & fee	VRS-ZJQ-QEYP dated 03-03-2024 Rs 30,000/- dated 28-02-2024 (Slip No. 0131673939)
	Pharmacological Group	Flusher
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	500gm, 1000gm, and 5000gm; Decontrolled
	Me-too status	Neyphralyte Powder of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071072)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Poultry, cattle **Shortcomings:** ➢ Clarification regarding applied formulation is required since **Magnesium chloride** is mentioned in composition on form-5 while **Magnesium sulphate** is mentioned in master formula. Accordingly, provide evidence of applied formulation already approved by DRAP (generic/me-too) alongwith registration number, brand name and name of the firm, ➢ Submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Deferred for following:	

	• **Clarification regarding applied formulation since Magnesium chloride is mentioned in composition on form-5 while Magnesium sulphate is mentioned in master formula. Accordingly, provide evidence of applied formulation already approved by DRAP (generic/me-too) alongwith registration number, brand name and name of the firm,** • **Rs.7500/- for correction in finished product specifications before issuance of registration letter.**	
450.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR Fahsfo-Med Oral Powder
	Composition	Each Kg contains: Fosfomycin Calcium ..... 200gm Tylosin Tartrate ..... 100gm Fructose ..... 180gm Sodium Phosphate ..... 150gm Magnesium Sulphate 100gm
	Tracking Id, date & fee	Y1H-HVH-MEGR dated 03-03-2024 Rs 30,000/- dated 28-02-2024 (Slip No. 2734826973)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	500gm, 1000gm, and 5000gm; Decontrolled
	Me-too status	Fosiril Powder of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 118610)
	GMP status	New Section
	Remarks of the Evaluator	**Shortcomings:** ➢ Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product and finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
451.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR Empro-Med Oral powder
	Composition	Each Kg contains: Amprolium HCl..... 980gm

	Tracking Id, date & fee	6Q9-98D-BUB6 dated 03-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 98651405)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	500gm, 1000gm, and 5000gm; Decontrolled
	Me-too status	Ampro-Forte Oral Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113524)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** calves, goats, sheep and poultry **Shortcomings:** ➢ Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
452.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR C Lincomed oral powder
	Composition	Each gm contains: Lincomycin HCl..... 100 mg Colistin Sulphate..... 800,000 IU
	Tracking Id, date & fee	PJ6-ZEM-3BM9 dated 03-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 850196216)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	500gm, 1000gm, and 5000gm; Decontrolled
	Me-too status	Col-Link Powder of M/s Farm Aid Group, Haripur (Reg. No. 118584)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Poultry

		Shortcomings: ➢ Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product and finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

I. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.

CLB in its 294th meeting held on 27th December, 2023 has considered and approved the grant of following additional sections:

1. Injectable (General Antibiotic) (Veterinary) Section (New)
2. Injectable (Penicillin) (Veterinary) Section (New)
3. Injectable (General) (Veterinary) Section (New)
4. Injectable (Steroid) (Veterinary) Section (New)

Accordingly, firm has applied for following products for consideration by the Registration Board.

Section	No. of Applied Products	No. of Molecule Applied
Injectable (General Antibiotic) (Veterinary) Section (New)	29	10
Injectable (Penicillin) (Veterinary) Section (New)	23	10
Injectable (General) (Veterinary) Section (New)	38	10
Injectable (Steroid) (Veterinary) Section (New)	22	08

Injectable (General Antibiotic) (Veterinary) Section (New)
(29 Products/ 10 Molecules)

453.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APRO-EN-10 Injection 100ml
	Composition	Each ml contains: Enrofloxacin..... 100mg
	Tracking Id, date & fee	5WB-NTL-LG5V dated 23-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 7441098549)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Apa Enro 10 I Injection of M/s Vetynex Pharma, Lahore. (Reg. No.118490)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	

454.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APRO-EN-10 Injection 10ml
	Composition	Each ml contains: Enrofloxacin..... 100mg
	Tracking Id, date & fee	9QZ-TLN-W5H8 dated 28-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 78054545735)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Bio-E-Floxacin 10% Injection of M/s Bio-Labs (Pvt) Ltd., Islamabad (Reg. No. 117226)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
455.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APRO-EN-20 Injection 100ml
	Composition	Each ml contains: Enrofloxacin..... 200mg
	Tracking Id, date & fee	WNG-GTL-5NDV dated 23-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 495549909)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Penroxacin Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 118649)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
456.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APRO-EN-20 Injection 10ml
	Composition	Each ml contains: Enrofloxacin..... 200mg
	Tracking Id, date & fee	QH3-GSD-QPTN dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 23461476733)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Bio-E-Floxacin 20% Injection of M/s Bio-Labs (Pvt) Ltd., Islamabad (Reg. No. 117223)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
457.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APRO-EN-5 Injection 100ml

	Composition	Each ml contains: Enrofloxacin..... 50mg
	Tracking Id, date & fee	DU3-9NX-RQWM dated 23-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 051002155408)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Ganadexil 5% Solution for Injection of M/s Punjnad Pharma (Pvt) Ltd. Lahore. (Reg. No. 099328)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
458.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAFEN Injection 50ml
	Composition	Each ml contains: Florfenicol..... 30mg
	Tracking Id, date & fee	EXP-RQR-9XT3 dated 23-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 14477352)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Naflor Injection of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 043554)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
459.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAFEN Injection 10ml
	Composition	Each ml contains: Florfenicol..... 30mg
	Tracking Id, date & fee	9H5-MBL-MUJY dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 89888299080)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Naflor Injection of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 043554)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
460.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAFEN-30 Injection 50ml
	Composition	Each ml contains: Florfenicol..... 300mg
	Tracking Id, date & fee	2W4-214-JVVQ dated 23-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 5957874154)

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Resflo Injection of M/s Decent Pharma, Rawat, Islamabad. (Reg. No. 118566)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
461.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAFEN-30 Injection 10ml
	Composition	Each ml contains: Florfenicol..... 300mg
	Tracking Id, date & fee	HS3-DDH-TNUV dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 0424090361)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Hilfen Injection 300mg/ml of M/s Hilton Pharma (Pvt) Ltd., Karachi. (Reg. No. 099024)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
462.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Colin-S Injection 100ml
	Composition	Each ml contains: Spiramycin Adipate..... 125 mg Lincomycin HCl.....75 mg
	Tracking Id, date & fee	8TG-5NL-773U dated 23-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 1661771863)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	L-S Vetz Injection of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 118424)
	GMP status	New Section
	Remarks of the Evaluator	**Shortcomings:** Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
463.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Colin-S Injection 50ml
	Composition	Each ml contains: Spiramycin Adipate..... 125 mg Lincomycin HCl.....75 mg

	Tracking Id, date & fee	SU3-BLA-PXS3 dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 061487384)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Evercip Injection of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 118405)
	GMP status	New Section
	Remarks of the Evaluator	**Shortcomings:** Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
464.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Colin-S Injection 10ml
	Composition	Each ml contains: Spiramycin Adipate..... 125 mg Lincomycin HCl.....75 mg
	Tracking Id, date & fee	U9G-9R1-AP2A dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 0220476825)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Lincospira Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 046570)
	GMP status	New Section
	Remarks of the Evaluator	**Shortcomings:** Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
465.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Aplagent injection 100ml
	Composition	Each ml contains: Gentamycin as sulphate.....50mg Tylosin as Tartrate.....100mg
	Tracking Id, date & fee	6AX-M8E-LJHS dated 24-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 6105648898)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	APA Gentylo I Injection of M/s Vetynex Pharma, Lahore. (Reg. No. 118492)
	GMP status	New Section
	Remarks of the Evaluator	

	Decision: Approved.	
466.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Aplagent injection 50ml
	Composition	Each ml contains: Gentamycin as sulphate.....50mg Tylosin as Tartrate.....100mg
	Tracking Id, date & fee	89E-DAH-1Q4M dated 28-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 80240645485)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Tylogent Injection of M/s Nawal Pharmaceuticals, Taxila-Rawalpindi. (Reg. No. 113609)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
467.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Aplagent injection 10ml
	Composition	Each ml contains: Gentamycin as sulphate.....50mg Tylosin as Tartrate.....100mg
	Tracking Id, date & fee	4AG-XG9-LZQD dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 51378489)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Gtrise Injection of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 112178)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
468.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Aplaco-Cin Injection 50ml
	Composition	Each ml contains: Lincomycin (as HCl) .....50mg Spectinomycin (as HCl) 100mg
	Tracking Id, date & fee	SEZ-LX2-H57D dated 24-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 2145672126)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Stalin Injection of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 101463)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	

469.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAOX-5 Injection 100ml
	Composition	Each ml contains: Oxytetracycline HCl….50mg
	Tracking Id, date & fee	H64-5QY-9GBD dated 26-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 4505567140)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Oxyvetz 5% Injection of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No.116894)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
470.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAOX-5 Injection 50ml
	Composition	Each ml contains: Oxytetracycline HCl….50mg
	Tracking Id, date & fee	LUS-PSX-WN85 dated 26-02-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 53441311)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	A-Oxy-5% Injection of M/s Al-Habib Agencies, Rawalpindi (Reg. No. 118485)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
471.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAOX-10 Injection 100ml
	Composition	Each ml contains: Oxytetracycline as HCl….100mg
	Tracking Id, date & fee	3ZM-TGS-2M9B dated 26-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 362596065)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Oxyriq-10 Injection of M/s Baariq Pharmaceuticals, Lahore (Reg. No. 087130)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
472.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAOX-10 Injection 50ml

	Composition	Each ml contains: Oxytetracycline as HCl….100mg
	Tracking Id, date & fee	XP2-647-5PB3 dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 2079380390)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Oxyriq-10 Injection of M/s Baariq Pharmaceuticals, Lahore (Reg. No. 087129)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
473.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAOX-20 Injection 100ml
	Composition	Each ml contains: Oxytetracycline HCl….200mg
	Tracking Id, date & fee	VWY-4VZ-S8AM dated 26-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 399973328957)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	A-Oxy-20 LA Injection of M/s Al-Habib Agencies, Rawalpindi (Reg. No. 118486)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
474.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAOX-20 LA Injection 100ml
	Composition	Each 100ml contains: Oxytetracycline Base.....20gm
	Tracking Id, date & fee	B7L-TE3-A57E dated 26-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 46676332949)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Oxy Injection of M/s Mediexcel Pharmaceuticals, Islamabad (Reg. No. 102169)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
475.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAFLOX Injection 50ml
	Composition	Each ml contains: Oxytetracycline.....300 mg Flunixin Meglumine.....20 mg

	Tracking Id, date & fee	BAE-TNU-A4D2 dated 26-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 087960312213)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Oxy-Loxy Injection of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 117316)
	GMP status	New Section
	Remarks of the Evaluator	**Shortcomings:** Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
476.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Ketostrep LA Injection 100ml
	Composition	Each ml contains: Oxytetracycline as HCl……..200mg **Ketoprofen**.....30mg
	Tracking Id, date & fee	P6S-L4W-ZBWZ dated 26-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 470625527)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Ketocin Injection of M/s A & K Pharmaceutical, Faisalabad. (Reg. No.102101)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
477.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Ketostrep LA Injection 20ml
	Composition	Each ml contains: Oxytetracycline as HCl……..200mg **Ketoprofen**.....30mg
	Tracking Id, date & fee	AA3-ZDD-L7QM dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 30271366088)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	20ml; Decontrolled
	Me-too status	Oxyfen LA Injection of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore (Reg. No. 071091)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
478.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.

	Brand Name +Dosage Form + Strength	Ketostrep LA Injection 50ml
	Composition	Each ml contains: Oxytetracycline as HCl……..200mg **Ketoprofen**.....30mg
	Tracking Id, date & fee	RH9-5JL-5NG3 dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 95106582745)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Pro Cycline Injection of M/s Kayans Pharmaceuticals, Rawalpindi. (Reg. No. 111328)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
479.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLA-SDD Injection 100ml
	Composition	Each ml contains: Sulfadimidine Sodium.....33.33%
	Tracking Id, date & fee	58N-WNY-3HHD dated 26-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 97347217464)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Sulpha DM Injection of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad. (Reg. No. 078342)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
480.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	ENBROX Injection 50ml
	Composition	Each ml contains: Enrofloxacin.....10% Bromhexine.....0.5%
	Tracking Id, date & fee	DST-QTG-YRDV dated 26-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 569573843)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Cruser Injection of M/s Star Laboratories (Pvt) Ltd., Lahore. (Reg. No. 117305)
	GMP status	New Section
	Remarks of the Evaluator	**Shortcomings:** Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim (salt form) in line with reference product before issuance of registration letter.

	Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
481.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	ENBROX Injection 100ml
	Composition	Each ml contains: Enrofloxacin.....10% Bromhexine.....0.5%
	Tracking Id, date & fee	MWH-J8G-VHH9 dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 55270499)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Cruser Injection of M/s Star Laboratories (Pvt) Ltd., Lahore. (Reg. No. 117306)
	GMP status	New Section
	Remarks of the Evaluator	**Shortcomings:** Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim (salt form) in line with reference product before issuance of registration letter.
	Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
Injectable (Steroid) (Veterinary) Section (New) (22 Products/ 08 Molecules)		
482.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APIPRED Injection 50ml
	Composition	Each 100ml contains: **Prednisolone as Acetate**.....0.75gm **Dexamethasone as Sodium Phosphate**.....0.25gm
	Tracking Id, date & fee	XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469)
	Pharmacological Group	Adrenocortical steroid anti-inflammatory drug
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi (Reg. No. 043115)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, horse, sheep, dogs, cats **Shortcomings:** State role of Creatinine mentioned in master formula.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **role of Creatinine mentioned in master formula.**	
483.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APIPRED Injection 10ml

	Composition	Each 100ml contains: **Prednisolone as Acetate**.....0.75gm **Dexamethasone as Sodium Phosphate**.....0.25gm
	Tracking Id, date & fee	DR8-LBM-E7P6 dated 28-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 617855393808)
	Pharmacological Group	Adrenocortical steroid anti-inflammatory drug
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Camocort Injection of M/s Lawrance Pharma (Pvt) Ltd., Lahore. (Reg. No. 043220)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, horse, sheep, dogs, cats **Shortcomings:** State role of Creatinine mentioned in master formula.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **role of Creatinine mentioned in master formula.**	
484.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Predphen-14 Injection 50ml
	Composition	Each ml contains: **Prednisolone**.....10mg Chlorpheniramine Maleate.....4 mg
	Tracking Id, date & fee	TSG-VLL-WMNG dated 27-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 9029153240)
	Pharmacological Group	Steroid and anti-histamine drug
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Chlorphen-P Injection of M/s Alina Combine Pharmaceutical (Pvt) Ltd. Karachi (Reg. No. 052354)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, horse, sheep, goats, dogs, cats **Shortcomings:** • Submit revised master formula since Creatinine is mentioned. • Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Submission of revised master formula since Creatinine is mentioned.** • **fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.**	
485.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Predphen-14 Injection 10ml
	Composition	Each ml contains: **Prednisolone**.....10mg

		Chlorpheniramine Maleate.....4 mg
	Tracking Id, date & fee	ZYS-QSN-S76E dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 15931938196)
	Pharmacological Group	Steroid and anti-histamine drug
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	PC Jet Injection of M/s Grand Pharma (Pvt) Ltd., Rawat, Islamabad (Reg. No. 106757)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, horse, sheep, goats, dogs, cats **Shortcomings:** • Submit revised master formula since Creatinine is mentioned. • Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Submission of revised master formula since Creatinine is mentioned.** • **fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.**	
486.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Predphen-40 Injection 50ml
	Composition	Each ml contains: **Prednisolone Acetate**.....25mg Chlorpheniramine Maleate.....10 mg
	Tracking Id, date & fee	ZR9-NS9-GRLX dated 27-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 295607848277)
	Pharmacological Group	Steroid and anti-histamine drug
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Laphenra-35 Injection **(20ml)** of M/s International Pharma Labs. Lahore. (Reg. No. 099035)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, horse, sheep, goats, dogs, cats **Shortcomings:** • State role of Creatinine mentioned in master formula.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Role of Creatinine mentioned in master formula.**	
487.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Predphen-40 Injection 10ml
	Composition	Each ml contains: **Prednisolone Acetate**.....25mg Chlorpheniramine Maleate.....10 mg

	Tracking Id, date & fee	Q9Y-3JN-Y389 dated 01-03-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 9811226112)
	Pharmacological Group	Steroid and anti-histamine drug
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Chlorprem 35 Injection (10ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 113499)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, horse, sheep, goats, dogs, cats **Shortcomings:** • State role of Creatinine mentioned in master formula.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Role of Creatinine mentioned in master formula.**	
488.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAPRED-10 Injection 50ml
	Composition	Each ml contains: **Prednisolone Acetate**.....10mg
	Tracking Id, date & fee	PEJ-Z86-E9AD dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 2161644409)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Premsone 10 Injection of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 111333)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, calves, dogs, cats **Shortcomings:** Official monograph of the applied formulation is **available in USP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Rs. 7500/- for correction in finished product specifications before issuance of registration letter.**	
489.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAPRED-10 Injection 10ml
	Composition	Each ml contains: **Prednisolone Acetate**.....10mg
	Tracking Id, date & fee	W79-B9T-95XA dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 97330011971)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled

	Me-too status	GP-Pred Injection of M/s Grand Pharma (Pvt) Ltd., Rawat, Islamabad. (Reg. No. 111541)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, calves, dogs, cats **Shortcomings:** Official monograph of the applied formulation is **available in USP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Rs. 7500/- for correction in finished product specifications before issuance of registration letter.**	
490.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Aplapred-25 Injection 50ml
	Composition	Each ml contains: **Prednisolone**.....25mg
	Tracking Id, date & fee	QE2-4JD-PMP6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 8297734842)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Pedison 25 Injection of M/s Farm Aid Group, Haripur. (Reg. No. 114929)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, calves, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
491.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Aplapred-25 Injection 10ml
	Composition	Each ml contains: **Prednisolone**.....25mg
	Tracking Id, date & fee	1N2-UT3-JV55 dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 93244892)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Pedison 25 Injection of M/s Farm Aid Group, Haripur. (Reg. No. 114928)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, calves, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
492.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.

	Brand Name +Dosage Form + Strength	Aplapred-25 Injection 100ml
	Composition	Each ml contains: **Prednisolone**.....25mg
	Tracking Id, date & fee	GTH-85T-TB2B dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 2924899807)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Prednisolone 2.5 Injectable Solution of M/s Orient Traders International, Karachi. (Reg. No. 020771)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, calves, dogs, cats **Shortcomings:** APLAPRED-25 Injection **10ml** is mentioned on fee challan.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
493.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Apthason-1 Injection 50ml
	Composition	Each ml contains: **Dexamethasone as Sodium Phosphate**.....1mg
	Tracking Id, date & fee	B2J-8NX-P8UG dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 8283006151)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Decaprem 1% Injection of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111334)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, horse, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
494.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Apthason-2 Injection 50ml
	Composition	Each ml contains: **Dexamethasone Sodium Phosphate eq to Dexamethasone Phosphate** 2mg
	Tracking Id, date & fee	Z8E-D71-TM28 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 95279484075)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Dexacare Injection of M/s Vety Care Islamabad (Reg. No. 026528)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:**

		Cattle, horse, calves, sheep foals, goats, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
495.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Apthason-4 Injection 50ml
	Composition	Each ml contains: **Dexamethasone Sodium Phosphate eq to Dexamethasone base** 4mg
	Tracking Id, date & fee	VJN-J5R-3EA1 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 8424685840)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Dexamethasone Injection of M/s Amros Pharm Karachi (Reg. No. 020100)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Horse, sheep goats, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
496.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLA OTD Injection 50ml
	Composition	Each 100ml contains: Oxytetracycline.....15gm Tripelenamine HCl.....1gm **Dexamethasone**.....0.050gm
	Tracking Id, date & fee	VYS-ZMZ-U2BP dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 486847959218)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	OXY-TD Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 029666)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Horse, cattle, sheep goats, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
497.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	KENA-S Injection 100ml
	Composition	Each ml contains: Kanamycin Sulphate.....50mg Colistin Sulphate.....100000 IU Neomycin Sulphate.....50mg **Dexamethasone 21 Phosphate Sodium Salt**.....0.5 mg
	Tracking Id, date & fee	DRA-A2S-DN9Z dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 9136058509)
	Pharmacological Group	Steroid and antimicrobial

	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	K.C.N.D. Injection of M/s Tarobina Corp Lahore (Reg. No. 020065)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
498.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Typhendex-G Injection 50ml
	Composition	Each ml contains: Thiamphenicol.....200mg Tylosin.....57.5mg **Prednisolone as Acetate**.....5mg
	Tracking Id, date & fee	8ZA-4EN-BNQD dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 764377478330)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Tylopen Injection of M/s Selmore Agencies (Pvt) Ltd., Lahore (Reg. No. 058815)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, calf, sheep, goats **Shortcomings:** Specify salt form of Tylosin
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and complete salt form of Tylosin.	
499.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Typhendex-G Injection 10ml
	Composition	Each ml contains: Thiamphenicol.....200mg Tylosin.....57.5mg **Prednisolone as Acetate**.....5mg
	Tracking Id, date & fee	4ZA-VRV-J69N dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 855673114)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Tylopen Injection of M/s Selmore Agencies (Pvt) Ltd., Lahore (Reg. No. 058815)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, calf, sheep, goats **Shortcomings:** Specify salt form of Tylosin

	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and complete salt form of Tylosin.	
500.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Tydogen Injection100ml
	Composition	Each 100ml contains: Tylosin Tartrate.....15gm Gentamycin Sulphate.....6gm **Dexamethasone**.....0.0265gm Chlorpheniramine.....0.750gm
	Tracking Id, date & fee	NX7-G19-DGBJ dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 92478096714)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Tylo-Combisone Injectable Solution of M/s Mustafa Brothers, Faisalabad (Reg. No. 053948)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock, poultry **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.	
501.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Tydogen Injection 10ml
	Composition	Each 100ml contains: Tylosin Tartrate.....15gm Gentamycin Sulphate.....6gm **Dexamethasone**.....0.0265gm Chlorpheniramine.....0.750gm
	Tracking Id, date & fee	6PV-J4N-EMNR dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 071348776314)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Genta Combisone Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 046696)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock, poultry **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.

	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.	
502.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Tydogen Injection 50ml
	Composition	Each 100ml contains: Tylosin Tartrate.....15gm Gentamycin Sulphate.....6gm **Dexamethasone**.....0.0265gm Chlorpheniramine.....0.750gm
	Tracking Id, date & fee	7RR-5HD-ZAYU dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 8726864866)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Genta Combisone Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 046696)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock, poultry **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.	
503.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Tydogen Injection 250ml
	Composition	Each 100ml contains: Tylosin Tartrate.....15gm Gentamycin Sulphate.....6gm **Dexamethasone**.....0.0265gm Chlorpheniramine.....0.750gm
	Tracking Id, date & fee	ZU3-1UJ-WV4W dated 01-03-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 915778667524)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	250ml; Decontrolled
	Me-too status	Genta Combisone Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 046696)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock, poultry **Shortcomings:** • Tydogen **50ml** Injection is mentioned on fee challan. • Confirmation of **relevant manufacturing facility**

		• Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of following: • **Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.** • Tydogen **50ml** Injection is mentioned on fee challan. • **Confirmation of relevant manufacturing facility**	
Injectable (Penicillin) (Veterinary) Section (New) (23 Products/ 10 Molecules)		
504.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	DICANE Injection 50ml
	Composition	Each ml contains: Procaine Penicillin G.....200000 IU Dihydrostreptomycin Sulfate.....250 mg **Dexamethasone**.....1mg
	Tracking Id, date & fee	2ME-JA3-8JMQ dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 228453807)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Dexa-SP Injection of M/s Atzan Pharmaceuticals, Sargodha (Reg. No. 049533)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Horse, cattle, sheep goats, dogs, poultry
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
505.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	AP-STREP-D Injection 50ml
	Composition	Each ml contains: Ampicillin Trihydrate.....100mg Colistin Sulfate.....250000 IU **Dexamethasone Acetate**.....0.5 mg
	Tracking Id, date & fee	7J2-5ML-JL4D dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 80191181)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Amcicoli-D Injection of M/s Atzan Pharmaceuticals, Sargodha (Reg. No. 049535)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock, poultry
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
506.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.

	Brand Name +Dosage Form + Strength	APLAMOX-15 LA Injection 100ml
	Composition	Each ml contains: Amoxicillin As Trihydrate.....150 mg
	Tracking Id, date & fee	TEU-H35-VEMT dated 26-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 435159422)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Amoxizon 15% LA Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119713)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, sheep, dogs, cats and poultry
	Decision: Approved.	
507.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAMOX-15 LA Injection 50ml
	Composition	Each ml contains: Amoxicillin As Trihydrate.....150 mg
	Tracking Id, date & fee	NJ4-Y46-31RA dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 632848989740)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Amoxizon 15% LA Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119712)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, sheep, dogs, cats and poultry
	Decision:Approved.	
508.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAMOX-20 LA Injection 50ml
	Composition	Each ml contains: Amoxicillin As Trihydrate.....200 mg
	Tracking Id, date & fee	WJ4-Z98-QD87 dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 008644674)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Amoxizon 20% LA Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119715)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock and poultry
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	

509.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAMOX-20 LA Injection 100ml
	Composition	Each ml contains: Amoxicillin As Trihydrate.....200 mg
	Tracking Id, date & fee	D5Y-2RZ-L4LS dated 26-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 4311695622)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Amoxizon 20% LA Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119716)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock and poultry
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
510.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAMOX-25 LA Injection 100ml
	Composition	Each ml contains: Amoxicillin Trihydrate.....250 mg (eq. to base 200mg)
	Tracking Id, date & fee	EWV-8PJ-TQP8 dated 26-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 9417356450)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Amoxizon 20% LA Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119716)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock and poultry ➢ **Same formulation applied at Sr. No. 509 with brand name APLAMOX-20 LA Injection 100ml vide tracking ID D5Y-2RZ-L4LS dated 26-02-2024**
	Decision: Registration Board disposed of the instant application since same formulation applied with brand name APLAMOX-20 LA Injection 100ml vide tracking ID D5Y-2RZ-L4LS dated 26-02-2024 is approved in instant meeting.	
511.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLOSTIN Injection 100ml
	Composition	Each ml contains: Amoxicillin as Trihydrate.....100mg Colistin Sulphate.....250000IU
	Tracking Id, date & fee	9W8-SDT-48Y7 dated 26-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 78986513)
	Pharmacological Group	Penicillin antibiotic

	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Lions-Mox-C Liquid Injection of M/s Bio-Labs (Pvt) Ltd., Islamabad (Reg. No. 118601)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock and poultry
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
512.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLOSTIN Injection 50ml
	Composition	Each ml contains: Amoxicillin as Trihydrate.....100mg Colistin Sulphate.....250000IU
	Tracking Id, date & fee	8QV-BMV-NLL9 dated 28-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 9907096508)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Colimoxin Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 034576)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock and poultry
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
513.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Aplacin Injection 100ml
	Composition	Each ml contains: Amoxicillin Trihydrate.....150mg Gentamycin Sulfate eq to Gentamycin.....40mg
	Tracking Id, date & fee	485-R79-6H33 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 734842424)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	AMOVET-GT Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi (Reg. No. 118398)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, buffalo, sheep, goat and poultry **Shortcomings:** Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

514.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Aplacin Injection 50ml
	Composition	Each ml contains: Amoxicillin Trihydrate.....150mg Gentamycin Sulfate eq to Gentamycin.....40mg
	Tracking Id, date & fee	A9X-Z7Q-SSP6 dated 28-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 478850229)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Amoxigen Injection of M/s Bio-Labs (Pvt) Ltd., Islamabad (Reg. No.117231)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, buffalo, sheep, goat and poultry **Shortcomings:** Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product before issuance of registration letter.
	Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
515.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APS-LA Injection 50ml
	Composition	Each ml contains: Benzathin Penicillin G.....100000IU Procaine Penicillin G.....150000IU Dihydrostreptomycin Sulfate Base.....200mg
	Tracking Id, date & fee	5TP-NDG-UYJ9 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 03895556481)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	MPPS-LA Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119719)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, horse, sheep, goat and poultry
	Decision: Approved.	
516.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APS-LA 20ml Injection
	Composition	Each ml contains: Benzathin Penicillin G.....100000IU Procaine Penicillin G.....150000IU Dihydrostreptomycin Sulfate Base.....200mg
	Tracking Id, date & fee	BJB-YDL-XUN7 dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 856519596588)
	Pharmacological Group	Penicillin antibiotic

	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	20ml; Decontrolled
	Me-too status	Pencin-LA Injection of M/s Star Laboratories (Pvt) Ltd., Lahore. (Reg. No. 063626)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, horse, sheep, goat and poultry
	Decision: Approved.	
517.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APS-LA 100ml Injection
	Composition	Each ml contains: Benzathin Penicillin G.....100000IU Procaine Penicillin G.....150000IU Dihydrostreptomycin Sulfate Base.....200mg
	Tracking Id, date & fee	A95-2DT-Z1SZ dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 00221317846)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Pencin-LA Injection of M/s Star Laboratories (Pvt) Ltd., Lahore. (Reg. No. 063626)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, horse, sheep, goat and poultry
	Decision: Approved.	
518.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Strep-G 450 Injection 50ml
	Composition	Each ml contains: Procaine Penicillin G.....200mg Dihydrostreptomycin.....250mg
	Tracking Id, date & fee	S45-HGR-57EM dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 344660534969)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Vetmycin-G Injection of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 084962)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
519.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Strep-G 400 Injection 50ml
	Composition	Each ml contains: Procaine Penicillin G.....200mg Dihydrostreptomycin Sulphate eq. to Dihydrostreptomycin 200mg

	Tracking Id, date & fee	8JE-YM1-8X3L dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 21492339063)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Pirate Injection of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No. 112167)
	GMP status	New Section
	Remarks of the Evaluator	**Shortcomings:** Official monograph of the applied formulation is **available in USP.** Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
520.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAMYCIN-15 Injection 100ml
	Composition	Each ml contains: Ampicillin Trihydrate.....150 mg
	Tracking Id, date & fee	T3G-5VN-7MVB dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 33177189715)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Ampicon Injection 150. 15% of M/s Vetcon Pharma Azad Kashmir (Reg. No. 012872)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, cats, dogs **Shortcomings:** Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
521.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAMYCIN-10 Injection 100ml
	Composition	Each ml contains: Ampicillin Trihydrate.....100 mg
	Tracking Id, date & fee	E6D-ZTA-DPV2 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 8561472922)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Ampi Rolds 10% Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109208)

	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, buffalo, horse, calves, sheep, goat, cats, dogs, poultry **Shortcomings:** Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
522.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAMYCIN-20 Injection 100ml
	Composition	Each ml contains: Ampicillin Trihydrate.....200 mg
	Tracking Id, date & fee	7N2-56N-L28M dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 627732590847)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Ampi Rolds 20% Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109211)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, cats, dogs **Shortcomings:** Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
523.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	CLAPEN 50ml Injection
	Composition	Each ml contains: Amoxicillin as Trihydrate.....140mg Clavulanic Acid.....35mg
	Tracking Id, date & fee	7L2-8WB-TS7B dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 39472926283)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Moxanic Injection of M/s Bio-Labs (Pvt) Ltd., Islamabad (Reg. No. 117233)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Livestock, dogs
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	

524.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	CLAPEN 20ml Injection
	Composition	Each ml contains: Amoxicillin as Trihydrate.....140mg Clavulanic Acid.....35mg
	Tracking Id, date & fee	UP4-LAP-RS92 dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 3077491072)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	20ml; Decontrolled
	Me-too status	Pri-Clav Injection **(50ml and 100ml)** of M/s Prix Pharmaceutica, Lahore. (Reg. No.102138 and 102139)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Livestock, dogs
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
525.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	CLAPEN 100ml Injection
	Composition	Each ml contains: Amoxicillin as Trihydrate.....140mg Clavulanic Acid.....35mg
	Tracking Id, date & fee	NGH-R24-23GW dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 85129869)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Pri-Clav Injection (100ml) of M/s Prix Pharmaceutica, Lahore. (Reg. No. 102139)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Livestock, dogs
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
526.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAMCIL Injection 100ml
	Composition	Each ml contains: Ampicillin as Trihydrate.....125mg Cloxacillin as Sodium.....125mg
	Tracking Id, date & fee	J35-N2Q-D4YP dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 296172994219)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Harray Cloxin 250 Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109193)

	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Livestock, poultry
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
Injectable (General) (Veterinary) Section (New) (38 Products/ 10 Molecules)		
527.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APCYNO-125 Injection 100ml
	Composition	Each ml contains: Cyanocobalamin.....125mcg
	Tracking Id, date & fee	V4V-DXJ-D8PE dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 61352737035)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	V-12 Injection (**50ml**) of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 117000)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Sheep, goats, Dogs, cats, calves, foals, cattle, horses **Shortcomings:** Official monograph of the applied formulation is **available in USP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
528.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APCYNO-250 Injection 100ml
	Composition	Each ml contains: Cyanocobalamin.....250mcg
	Tracking Id, date & fee	Q25-BXZ-9P61 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 27056099597)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Cormax Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi. (Reg. No. 117157)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Sheep, goats, Dogs, cats, calves, foals, cattle, horses **Shortcomings:** Official monograph of the applied formulation is **available in USP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.

	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
529.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APCYNO-250 Injection 50ml
	Composition	Each ml contains: Cyanocobalamin.....250mcg
	Tracking Id, date & fee	NGJ-JG8-EZPS dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 7516426326)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Amvit-250 Injection of M/s Aamster Laboratories, Rawat, Islamabad (Reg. No. 109911)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Sheep, goats, Dogs, cats, calves, foals, cattle, horses **Shortcomings:** Official monograph of the applied formulation is **available in USP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
530.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APCYNO-250 Injection 10ml
	Composition	Each ml contains: Cyanocobalamin.....250mcg
	Tracking Id, date & fee	UYM-TGM-DVMS dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 7301001929)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Cyanocob 250 Injection of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No.072692)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Sheep, goats, Dogs, cats, calves, foals, cattle, horses **Shortcomings:** Official monograph of the applied formulation is **available in USP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
531.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.

	Brand Name +Dosage Form + Strength	APCYNO-100 Injection 100ml
	Composition	Each ml contains: Cyanocobalamin.....1000mcg
	Tracking Id, date & fee	VMM-E1U-B5Z8 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 86194423)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Cynozon Extra Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No.119706)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Sheep, goats, Dogs, cats, calves, foals, cattle, horses **Shortcomings:** Official monograph of the applied formulation is **available in USP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
532.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLACAM-7.5 Injection 50ml
	Composition	Each ml contains: Meloxicam.....7.5mg
	Tracking Id, date & fee	HTV-G82-GUVV dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 0643734567)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Diclozon 7.5 Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119695)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Sheep, goats, Dogs, cats, cattle, horses **Shortcomings:** Official monograph of the applied formulation is **available in BP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
533.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLACAM-7.5 Injection 100ml
	Composition	Each ml contains: Meloxicam.....7.5mg
	Tracking Id, date & fee	71G-56E-LYUJ dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 1805146621)

	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Diclozon 7.5 Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119696)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Sheep, goats, Dogs, cats, cattle, horses **Shortcomings:** Official monograph of the applied formulation is **available in BP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
534.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLACAM-10 Injection 20ml
	Composition	Each ml contains: Meloxicam.....10mg
	Tracking Id, date & fee	YX2-MZE-9S7G dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 64954206442)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	20ml; Decontrolled
	Me-too status	Meloxi-10 Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049643)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Sheep, goats, Dogs, cats, cattle, horses **Shortcomings:** Official monograph of the applied formulation is **available in BP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
535.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLACAM-10 Injection 100ml
	Composition	Each ml contains: Meloxicam.....10mg
	Tracking Id, date & fee	AXB-5A5-TQZN dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 3985509631)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Meloxi-10 Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049643)

	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Sheep, goats, Dogs, cats, cattle, horses **Shortcomings:** Official monograph of the applied formulation is **available in BP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
536.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLACAM-10 Injection 50ml
	Composition	Each ml contains: Meloxicam.....10mg
	Tracking Id, date & fee	BGQ-EZD-BJH3 dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 83041391)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Meloxi-10 Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049643)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, buffalo, Sheep, camel, goats, Dogs, cats, horses **Shortcomings:** Official monograph of the applied formulation is **available in BP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
537.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLACAM-20 Injection 50ml
	Composition	Each ml contains: Meloxicam.....20mg
	Tracking Id, date & fee	7E9-6E6-LT66 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 0462074241)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Diclozon 20 Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119692)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, buffalo, Sheep, camel, goats, Dogs, cats, horses **Shortcomings:** Official monograph of the applied formulation is **available in BP**. Firm shall submit Rs. 7500/- for

		correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
538.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLACAM-20 Injection 100ml
	Composition	Each ml contains: Meloxicam.....20mg
	Tracking Id, date & fee	WSL-1WR-PNL6 dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 9275332800)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Elvosol Star Injection of M/s Elko Organization (Pvt) Ltd., Karachi. (Reg. No. 063733)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, buffalo, Sheep, camel, goats, Dogs, cats, horses **Shortcomings:** Official monograph of the applied formulation is **available in BP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
539.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLACAM-20 Injection 10ml
	Composition	Each ml contains: Meloxicam.....20mg
	Tracking Id, date & fee	3WQ-15E-VEG3 dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 76085443)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Elvosol Star Injection of M/s Elko Organization (Pvt) Ltd., Karachi. (Reg. No. 063733)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, buffalo, Sheep, camel, goats, Dogs, cats, horses **Shortcomings:** Official monograph of the applied formulation is **available in BP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

540.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLACAM-5 Injection 50ml
	Composition	Each ml contains: Meloxicam.....5mg
	Tracking Id, date & fee	JB6-R63-5BL1 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 801744231)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 108991)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, buffalo, Sheep, camel, goats, Dogs, cats, horses **Shortcomings:** Official monograph of the applied formulation is **available in BP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
541.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLACAM-5 Injection 100ml
	Composition	Each ml contains: Meloxicam.....5mg
	Tracking Id, date & fee	PLM-45G-AXVG dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 164369059207)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 108992)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, buffalo, Sheep, camel, goats, Dogs, cats, horses **Shortcomings:** Official monograph of the applied formulation is **available in BP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
542.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLA AD3E Injection 100ml

	Composition	Each ml contains: Vitamin A.....100000 IU Vitamin D3.....40000 IU Vitamin E.....40mg
	Tracking Id, date & fee	243-P2P-4U4H dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 1205134962)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Ad Vetz Injection of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 117207)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, calves, sheep, goats, horses
	Decision: Approved.	
543.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLA AD3E Injection 50ml
	Composition	Each ml contains: Vitamin A.....100000 IU Vitamin D3.....40000 IU Vitamin E.....40mg
	Tracking Id, date & fee	95S-UA2-3Z5D dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 24250160)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Vital Forte Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 118456)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, calves, sheep, goats, horses
	Decision: Approved.	
544.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLA AD3E Injection 20ml
	Composition	Each ml contains: Vitamin A.....100000 IU Vitamin D3.....40000 IU Vitamin E.....40mg
	Tracking Id, date & fee	8WN-R1X-47UA dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 3631729002)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	20ml; Decontrolled
	Me-too status	ADEKA Injection of M/s A & K Pharmaceutical, Faisalabad. (Reg. No.075792)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, calves, sheep, goats, horses
	Decision: Approved.	

545.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	MULTEIN Injection 250ml
	Composition	Each 100ml contains: L-Caritine…….....500mg Pyridoxine HCl….……...15mg Cyanocobalamine……...3mg DL-Acetylmethionine…....2gm L-Arginine…….....240mg L-Citruline…….……....120mg Glycine……....150mg Aspartic Acid……...150mg Fructose……...5gm Thiotic Acid……..20mg L-Ornithine……120mg L-Lysine……...…..50mg Taurine……150mg Glutamic Acid……...150mg Sorbitol……....8gm
	Tracking Id, date & fee	PZB-A2D-PB2Y dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 78871432)
	Pharmacological Group	Multivitamins and amino acids
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	250ml; Decontrolled
	Me-too status	Vetzpower Injection of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 088074)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, buffalo, calves, sheep, goats, horses, lamb and goat kids, dogs and cats, poultry **Shortcomings:** • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for confirmation of relevant manufacturing facility.	
546.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	MENIXIN-50 Injection 50ml
	Composition	Each ml contains: Flunixin Meglumine…….....50mg
	Tracking Id, date & fee	MHW-Y2R-R3S7 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 08706259982)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Floxon Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119708)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, camels, sheep, goats, horses, dogs **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product and FPP

		specifications as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Approved. Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
547.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	MENIXIN-50 Injection 20ml
	Composition	Each ml contains: Flunixin Meglumine…….....50mg
	Tracking Id, date & fee	EU8-462-72RH dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 9204837280)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	20ml; Decontrolled
	Me-too status	Fluxim-5% Injection of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No.109942)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, camels, sheep, goats, horses, dogs **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product and FPP specifications as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
548.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	MENIXIN-50 Injection 10ml
	Composition	Each ml contains: Flunixin Meglumine…….....50mg
	Tracking Id, date & fee	BNX-UNR-V23T dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 3077206224)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Floxon Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119707)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, camels, sheep, goats, horses, dogs **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product and FPP specifications as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

549.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	MENIXIN-83 Injection 50ml
	Composition	Each ml contains: Flunixin Meglumine…….....83mg
	Tracking Id, date & fee	839-AXW-XG95 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 62997364746)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117364)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, camels, sheep, goats, horses, dogs **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
550.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	MENIXIN-83 Injection 20ml
	Composition	Each ml contains: Flunixin Meglumine…….....83mg
	Tracking Id, date & fee	MAB-8VS-PLMA dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 80219906)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	20ml; Decontrolled
	Me-too status	Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, camels, sheep, goats, horses, dogs **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
551.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAFENIK Injection 50ml
	Composition	Each ml contains: **Ketoprofen**…….....100mg
	Tracking Id, date & fee	ZB1-8UN-L1LA dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 0893442558)

	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Ketoject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 043141)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
552.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAFENIK Injection 100ml
	Composition	Each ml contains: **Ketoprofen**…….....100mg
	Tracking Id, date & fee	Z91-16X-2WWA dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 33091851175)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Ketoject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 043141)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
553.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAFENIK Injection 20ml
	Composition	Each ml contains: **Ketoprofen**…….....100mg
	Tracking Id, date & fee	BGU-193-6QQ1 dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 667493224)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	20ml; Decontrolled
	Me-too status	Ketoject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 043141)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
554.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	IVERCLOTIN Injection 50ml
	Composition	Each ml contains: Ivermectin.....10mg Clorsulon.....100mg

	Tracking Id, date & fee	BJJ-A3J-AZ7V dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 5424954399)
	Pharmacological Group	Antiparasitic/anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	EVO-C Injection of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 117311)
	GMP status	New Section
	Remarks of the Evaluator	**Shortcomings:** Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
555.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	IVERCLOTIN Injection 10ml
	Composition	Each ml contains: Ivermectin.....10mg Clorsulon.....100mg
	Tracking Id, date & fee	576-AW6-UML4 dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 11312122)
	Pharmacological Group	Antiparasitic/anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Mecloxon-110 Injection of M/s Farm Aid Group, Haripur. (Reg. No. 117257)
	GMP status	New Section
	Remarks of the Evaluator	**Shortcomings:** Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
556.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	IVERCLOTIN Injection 100ml
	Composition	Each ml contains: Ivermectin.....10mg Clorsulon.....100mg
	Tracking Id, date & fee	DVH-8AL-TV28 dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 65023269734)
	Pharmacological Group	Antiparasitic/anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Mecloxon-110 Injection of M/s Farm Aid Group, Haripur. (Reg. No. 117259)
	GMP status	New Section

	Remarks of the Evaluator	**Shortcomings:** Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Approved. Firm shall submit Rs.7500/- for pre-approval change/correction in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
557.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	NIXINIL-34 Injection 100ml
	Composition	Each ml contains: Nitroxynil.....340mg
	Tracking Id, date & fee	LVZ-3JL-6R51 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 5180047130)
	Pharmacological Group	Antiparasitic/anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Nitrox Injection of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 117221)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, sheep, goats
	Decision: Approved.	
558.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	NIXINIL-34 Injection 10ml
	Composition	Each ml contains: Nitroxynil.....340mg
	Tracking Id, date & fee	XE9-HDH-U24Y dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 17191961)
	Pharmacological Group	Antiparasitic/anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Nitroxl Forte Injection of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106697)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, sheep, goats
	Decision: Approved.	
559.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	NIXINIL-20 Injection 50ml
	Composition	Each ml contains: Nitroxynil.....200mg
	Tracking Id, date & fee	HH1-T1R-8H15 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 95749475545)
	Pharmacological Group	Antiparasitic/anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled

	Me-too status	Tronox-200 Injection **(100ml)** of M/s Nawal Pharmaceuticals, Taxila, Rawalpindi. (Reg. No. 099040)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, sheep, goats
	Decision: Approved.	
560.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	NIXINIL-20 Injection 10ml
	Composition	Each ml contains: Nitroxynil.....200mg
	Tracking Id, date & fee	NHU-L2V-WH25 dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 93496352742)
	Pharmacological Group	Antiparasitic/anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Tronox-200 Injection **(100ml)** of M/s Nawal Pharmaceuticals, Taxila, Rawalpindi. (Reg. No. 099040)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, sheep, goats
	Decision: Approved.	
561.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	IMIDOCA Injection 50ml
	Composition	Each ml contains: Imidocarb Dipropionate.....120 mg
	Tracking Id, date & fee	M3Y-3QM-Y434 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 05423370)
	Pharmacological Group	Antiparasitic/anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Imidobar Injection of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 117367)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, sheep, goats, horses, donkey, dogs **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Approved. Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
562.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	IMIDOCA 10ml Injection
	Composition	Each ml contains: Imidocarb Dipropionate.....120 mg
	Tracking Id, date & fee	8EY-YWB-VS7Z dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 56073568769)

	Pharmacological Group	Antiparasitic/anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Bioimido Injection of M/s Bio-Labs (Pvt) Ltd., Islamabad (Reg. No. 118602)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Cattle, sheep, goats, horses, donkey, dogs **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Approved. Firm shall submit Rs.30,000/- for pre-approval change/correction in label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
563.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APYMYRA Injection 50ml
	Composition	Each ml contains: Mepyramine Maleate.....50mg
	Tracking Id, date & fee	8Q7-MD1-X57Y dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 5327510506)
	Pharmacological Group	Antihistamine/anti-allergic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Meprax Injection of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 112258)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Livestock, sheep, dogs
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	
564.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APYMYRA Injection 10ml
	Composition	Each ml contains: Mepyramine Maleate.....50mg
	Tracking Id, date & fee	AYX-YQZ-1GAT dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 7954955550)
	Pharmacological Group	Antihistamine/anti-allergic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Allerginil Liquid Injection of M/s Sanna Laboratories, Faisalabad (Reg. No. 069623)
	GMP status	New Section
	Remarks of the Evaluator	**Target Species:** Livestock, sheep, dogs
	Decision: Approved. Moreover, Registration Board advised the applicant to clearly mention specific target species on label.	

Agenda Item:
Registration applications of new section:
M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan was granted following new sections on 13.01.2022:
a) Sachet section (general)
b) Oral dry powder suspension (general)

565.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-12-2021/ based on inspection conducted on 24/11/2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 13-01-2022 specifying sachet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21514 dated 31/08/2023
	Details of fee submitted	PKR 30,000/- Dated 04-08-2023
	The proposed proprietary name / brand name	**Raceka 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Racecadotril…..10mg
	Pharmacotherapeutic Group of (API)	Antidiarrheal
	Pharmaceutical form of applied drug	Granules for oral Suspension
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	16's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules For Oral Suspension, Bioproject Limited United Kingdom
	For generic drugs (me-too status)	Racedo 10mg Sachet Highnoon Laboratories Ltd. 17.5 K.M. Multan Road, Lahore-Pakistan
	Name and address of API manufacturer.	Shandong Boyuan Pharmaceutical Co., Ltd Qiangjin Street, Jibei Economic Development Zone, Jinan, Shandong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature,

		structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Hidrasec 10 mg, Granules for oral suspension manufactured by Bioproject Limited United Kingdom Firm has submitted CDP results of their product against the innovator's product Hidrasec 10 mg, Granules for oral suspension in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Shandong Boyuan Pharmaceutical Co., Ltd Qiangjin Street, Jibei Economic Development Zone, Jinan, Shandong, China		
API Lot No.	22060IRO		
Description of Pack (Container closure system)	Aluminium Sachet		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-055NS02	T-055NS03	T-055NS04
Batch Size	500 Sachet	500 Sachet	500 Sachet
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	27-01-2023	27-01-2023	27-01-2023

No. of Batches		03
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. G/2/173) dated 29-01-2022 issued by Food and Drugs Control Administration CHINA. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
566.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-12-2021/ based on inspection conducted on 24/11/2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 13-01-2022 specifying sachet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 21515 dated 31/08/2023

	Details of fee submitted	PKR 30,000/- Dated 04-08-2023
	The proposed proprietary name / brand name	**Raceka 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Racecadotril…..30mg
	Pharmacotherapeutic Group of (API)	Antidiarrheal
	Pharmaceutical form of applied drug	Granules for oral suspension
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	16's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 30 mg, Granules for oral suspension
	For generic drugs (me-too status)	Racedo 10mg Sachet Highnoon Laboratories Ltd. 17.5 K.M. Multan Road, Lahore-Pakistan
	Name and address of API manufacturer.	Shandong Boyuan Pharmaceutical Co., Ltd., Qiangjin Street, Jibei Economic Development Zone, Jinan, Shandong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Hidrasec 10 mg, Granules for oral suspension manufactured by Bioproject Limited United Kingdom Firm has submitted CDP results of their product against the innovator's product Hidrasec 10 mg, Granules for oral suspension in 3 dissolution medias.		
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
STABILITY STUDY DATA				
Manufacturer of API		Shandong Boyuan Pharmaceutical Co., Ltd Qiangjin Street, Jibei Economic Development Zone, Jinan, Shandong, China		
API Lot No.		22060IRO		
Description of Pack (Container closure system)		Aluminium Sachet		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T-055NS02	T-055NS03	T-055NS04
Batch Size		500 Sachet	500 Sachet	500 Sachet
Manufacturing Date		02-2023	02-2023	02-2023
Date of Initiation		27-01-2023	27-01-2023	27-01-2023
No. of Batches		03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. G/2/173) dated 29-01-2022 issued by Food and Drugs Control Administration CHINA. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).			
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
Remarks of Evaluator:				

Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
567.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-12-2021/ based on inspection conducted on 24/11/2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 13-01-2022 specifying sachet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17569 dated 13.07.2023
	Details of fee submitted	PKR 30,000/- (765590156418)
	The proposed proprietary name / brand name	**Fist - K Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Diclofenac Potassium ……. 50mg
	Pharmacotherapeutic Group of (API)	NSAID (Cyclo-oxygenase inhibitor)
	Pharmaceutical form of applied drug	Granules for oral suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	10’s , 20’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Italian Medicines Agency
	For generic drugs (me-too status)	Nil
	Name and address of API manufacturer.	Henan Dongtai Pharm., Co Ltd, No. 2 East Kangtai Road, Tangyin County Anyang City Henan China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general

		properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Catafast sachet 50mg, manufactured by Mipharm S.p.A., Milan, Italy Firm has submitted CDP results of their product against the innovator's product Catafast sachet 50mg in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Henan Dongtai Pharm., Co Ltd, No. 2 East Kangtai Road, Tangyin County Anyang City Henan China.		
API Lot No.	303210413-5		
Description of Pack (Container closure system)	Aluminium Sachet		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T 001	T 002	T 003
Batch Size	500 Sachet	500 Sachet	500 Sachet
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	26-09-2022	26-09-2022	26-09-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate issued by Food and Drugs Control Administration CHINA which is valid till 05.11.2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:
Sachet (General) Section-New, granted vide DRAP approval 1-18/92-Lic-Vol-III dated 13.01.2022**.**

Shortcomings:

1. DRAP attested invoice for import of the raw Diclofenac potassium.
2. Details of the products already granted registration in the sachet section.
3. Latest GMP certificate of the FPP manufacturer as the submitted one was valid till 24.09.2021.
4. Copy of valid DML of the FPP manufacturer.
5. Justification for not submitting quantitative aqueous pH solubility profile under 3.2.S.1.3.
6. The drug substance specifcations of the manufacturer are BP and you are referring USP specifcations. Please clarify that both of these monographs are harmonized in terms of specs, procedures and reference limits. (3.2.S.4.1 & 3.2.S.4.2)
7. Justification for not performing specificity for identification tests (3.2.S.3)
8. Submit the raw data for the testing of Diclofenac Potassium for API Batch No. 303210413-5 dated 18.09.2022.
9. The Stability data of drug substance submitted is not as per requirements laid down in guidance document (PE&R/GL/AF/004). Complete data is required under 3.2.S.7.
10. Clarify as BP specs are mentioned under composition in 3.2.P.1 however are testing API as per USP.
11. The applied formulation is not qualitatively similar with the reference product (Cambia of USFDA) in terms of excipients. Justify the same with appropriate references or data 3.2. P.1.
12. Any critical quality attributes of the API which are relevant to the formulation, e.g., particle size etc.,
13. Justify the quantities of excipients used in formulation during development with optimization studies. The avg. weight/ unit of your formulation is 1gm and reference product is about 800mg, how would you justify that additional quantity of expedients than innovator do not impact the dissolution/ absorption of the drug.
14. Details of the results on the suggested time points of dissolution of 12 units (sachets) of innovator and test product with batch No. in a table format of three physiological media for CDP as the submitted details are insufficient.
15. CoA of Catafast Sachet indicating batch No. generated by you for Pharmaceutical Equivalence testing.

16. Pictures of the reference product (Catafast) indicating Lot No., mfg and expiry dates and shipment details (if any).
17. Justification of discussing manufacturing process and critical control points under the 3.2. P.2.2.3.
18. Justify that the container closure material is same as of innovator products as stated in 3.2.P.2.4
19. In process tests (if any) and their procedures required during manufacturing process need to be incorporated in flow chart 3.2.P.3.3 for final blend before filling and their specs and limits need to be defined in the in 3.2.P.3.4
20. Process performance validation/ qualification protocol is not submitted
21. Clarification that validation report is generated while using real time equipments for submitted three batches.
22. Submit the recent monographs of the excipients for the stated reference specifications i.e. BP.
23. Certificate of analysis of all excipient used in the formulation by the FPP manufacturer and the details of their sources as well.
24. Clarify that the specifcations limits for pH are stated as 7-11.5 under 3.2.P.5.1 however as per USP monograph it is 7.0-9.0.
25. The method of testing for TAMC and TYMC is not in line with USP General Chapter (61) and method for test for absence of E.coli needs to be submitted.
26. The batch No. pf API provided in the BMR of three batches is not same as submitted in the drug substance part 3.2.S.
27. The copies of raw material store ledger/book dispensing, log books log books of the manufacturing equipments and QC labs for the three trail batches.
28. Justify the test for moisture content in FPP specifcations. The test procedure is not provided in 3.2.P.5.2.
29. Certificate of analysis of reference standards submitted under 3.2.P.6.
30. Justification for not conducting the test for TAMC & TYMC and tests for absence of E.*coli* during stability. However, the same were mentioned in the protocol.
31. Data logger reports for accelerated stability studies are not submitted.
32. Submit the stability data conducted as of today.

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

568.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Pvt Ltd., 14-Km Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals Pvt Ltd., 14-Km Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-12-2021 based on inspection conducted on 24/11/2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 13-01-2022 specifying Oral Dry Powder Suspension new
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No…. dated 01/06/2023
	Details of fee submitted	PKR 30,000/- Dated 26/05/2023
	The proposed proprietary name / brand name	**CLATHRO 125mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Clarithromycin……125mg

	Pharmacotherapeutic Group of (API)	Macrolide Antibiotics
	Pharmaceutical form of applied drug	oral suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	1's (60ml)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Clarithromycin 125mg/5ml Dry Suspension Sandoz B.V., Veluwezoom 22, 1327 AH Almere Nederland
	For generic drugs (me-too status)	Klaricid 125mg/5ml Dry Suspension Abbott Laboratories (Pakistan) Ltd.
	Name and address of API manufacturer.	Surge Laboratories (Private) Limited Pakistan 10th KM, Faisalabad Road Bikhi, District Sheikhupura –Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Klaricid 125mg/5ml Suspension manufactured by Abbott Laboratories Pakistan Limited Firm has submitted CDP results of their product against the innovator's product Klaricid 125mg/5ml Suspension in 3 dissolution medias.

	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
STABILITY STUDY DATA				
Manufacturer of API		Surge Laboratories (Private) Limited Pakistan 10th KM, Faisalabad Road Bikhi, District Sheikhupura – Pakistan.		
API Lot No.		CTM-1-663		
Description of Pack (Container closure system)		White Plastic Bottle		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T-001	T-002	T-003
Batch Size		300 bottles	300 bottles	300 bottles
Manufacturing Date		08-2022	08-2022	08-2022
Date of Initiation		27-08-2022	27-08-2022	27-08-2022
No. of Batches		03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. (189/2022-DRAP(AD-99778029213) dated 22/10/2022 issued by Drug Regulatory Authority of Pakistan. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 20-07-2022 specifying 18.5000Kg of clarithromycin. The invoice is cleared by dawn Shaigan Pharmaceuticals Pvt. Ltd.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
Under 1.6.5 (a) you have mentioned M/s Surge Laboratories (Pvt) Limited, Pakistan as API manufacturer, however as per record the aforesaid manufacturer is manufacturing bulk Clarithromycin Granules. You are hereby advised to submit the name and address of API manufacturer rather source of half finished product manufacturer. Under 1.6.5 (b) the approval of manufacturing facility of Clarithromycin API is required rather bulk Clarithromycin Granules. The drug substance i.e., Clarithromycin API information need to be submitted under 2.3.S and 3.2.S as required under DRAP guidance document.				

The manufacturing of Clarithromycin taste masked granules needs to be included in the Drug Product Modules being the part of drug product manufacturing.

The following information need to be submitted by M/s Surge Laboratories (Private) Limited Pakistan, 10th KM, Faisalabad Road Bikhi, District Sheikhupura:

a. Copies of DRAP attested invoices for purchase of Clarithromycin API along with Certificate of analysis.
b. Composition of Clarithromycin granules needs to be submitted in table format indicating quantities per dosage unit and function of each excipient with its reference to standard.
c. Overages added or not.
d. Description of container closure system.
e. Name of the reference/ branded product keeping in view the generic taste masked pellets have been developed.
f. Justification that the choice excipients is in line with the reference/ innovator product. In case different excipients have been used then justify and submit compatibility studies as well.
g. Optimization studies (if any) for confirming final the quantities of excipients.
h. Pharmaceutical equivalence studies.
i. Comparative dissolution studies in physiological media.
j. Manufacturing process development data along with the explanation of manufacturing enteric coated granules. This should be justified with experimental data or with reference literature which indicates that clarithromycin is degradable in gastric pH/ medium. The data of initial trails conducted (wherein 5:3 ratio uncoated granules were good for coating) will be valuable document for review.
k. Commercial batch formula with quantities of raw materials used.
l. Manufacturing process flow chart indicating input materials and In-process test.
m. Process qualification protocol and process performance qualification report with results of three commercial scale batches.
n. Under specifcations, justification is required for mentioning pH limits 3.5-7.0, however USP limits are 4.0-5.4.
o. Justification for dissolution specifcations for granules in two media and their limits.
p. Justification for assigning LOD specifications NMT 5% however as per pharmacopeia the specs are NMT 2%. Clarification is also required that in the manufacturing process at step: Drying and Unloading of Coated Granules of Clarithromycin you are drying the granules at 45-55^{0}C till to get LOD NMT 2% however the specs are assigned NMT 5%.
q. Justification for conducting heavy metals test.
r. Justification for not specifying the tests for impurities in specifcations.
s. Clarification required as Class III solvents are being used in the manufacturing process however their residual limits are not specified in the final specifcations.
t. Copies of monographs of the excipients as per pharmacopeial reference mentioned in dossier
u. Certificate of analysis of reference standards.
v. Evidence of availability of Gas Chromatograph for testing benzene in Acrypol 934 and EG/PEG in PEG 6000 and other quality tests required testing using Gas Chromatograph of other excipients.
w. Details of PEG batches recently purchased/ imported and tested for DEG/EG impurities in compliance to DRAP directives. CoA need to submitted as evidence.
x. Copy of approval of quota allocation from Control Drugs Division of DRAP for import/ purchase of acetone for batch No. K3587937 Mfg Date 08-2018 and Exp date 12-2022 GRN No: 19120035.
y. Stress testing study data as the API has been exposed to 80^{o}C during the manufacturing process form almost 10-12 hours for two times and also at 45-55^{0}C for attaining the desired moisture Limits
z. Justification for conducting tests for LOD and impurities in the stability testing.
aa. Stability data of last three batches under ongoing stability program.

Copy of the invoice of purchase of 18.5Kg of clarithromycin granules.

3.2. P.1 Justification for adding Citric acid and titanium dioxide in the in the formulation as the granules manufacturer has already added the same in the formulation. Moreover, the composition of plastic bottle along with description and composition of cap needs to be elaborated.

3.2. P.2 Justify that the composition of applied formulation is same as of Innovator/ reference product.

3.2.P.2.2.1 Details of the batch (Batch No., Mfg and expiry) of the reference product used for pharmaceutical equivalence and comparative dissolution.

Justification for adding the microbiological enumeration tests and tests for specified microorganisms in in pharmaceutical equivalence studies.

Details of the results on the suggested time points of dissolution of 12 units of innovator and test product with batch No. in a table format of three physiological media for CDP as the submitted details are insufficient and only at 6.8 pH (3.2.P.2.2.1) 3.2.P.4 Reference of specifcations for control of excipients. 3.2.P.5. Justify specification limits of LOD as the manufacturer providing the granules has limits NMT 5%. and limits for pH 3.5-7.0. The Certificate of analysis generated by you vide No. 14650 dated 23.07.2022 has LOD 2.23% for Batch (CTM-1-663) of Clarithromycin granules supplied by the source used for manufacturing of product. Please clarify how the LOD was reported less than 2% in the finished product. The Certificate of analysis generated by you vide No. 14650 dated 23.07.2022 reported pH 6.08 for Batch (CTM-1-663) of Clarithromycin granules supplied by the source used for manufacturing of product. Please clarify how the pH was reported within 4-5.4 for three batches of finished product. Certificate of analysis of reference standards submitted under 3.2. P.6. Justification that quantity per batch is justified w.r.t the tests needed to perform stability for proposed shelf life.		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings		
569.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Pvt Ltd., 14-Km Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals Pvt Ltd., 14-Km Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-12-2021 based on inspection conducted on 24/11/2021
	Evidence of approval of manufacturing facility	Oral Dry Powder Suspension (General) granted vide DRAP approval 1-18/92-Lic-Vol-III dated 13.01.2022.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16608 dated 04/07/2023
	Details of fee submitted	PKR 30,000/- Dated 26/05/2023
	The proposed proprietary name / brand name	**CLATHRO 250mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Clarithromycin……250mg
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotics
	Pharmaceutical form of applied drug	Oral Suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	1's (60ml)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Clarithromycin 125mg/5ml Dry Suspension Sandoz B.V., Veluwezoom 22, 1327 AH Almere Netherland
	For generic drugs (me-too status)	Klaricid 125mg/5ml Dry Suspension Abbott Laboratories (Pakistan) Ltd.

	Name and address of API manufacturer.	Surge Laboratories (Private) Limited Pakistan 10th KM, Faisalabad Road Bikhi, District Sheikhupura –Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Klaricid 125mg/5ml Suspension manufactured by Abbott Laboratories Pakistan Limited Firm has submitted CDP results of their product against the innovator's product Klaricid 125mg/5ml Suspension in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API		Surge Laboratories (Private) Limited Pakistan 10th KM, Faisalabad Road Bikhi, District Sheikhupura – Pakistan.
API Lot No.		CTM-1-663
Description of Pack (Container closure system)		White Plastic Bottle
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH

		Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T-001	T-002	T-003
Batch Size		300 bottles	300 bottles	300 bottles
Manufacturing Date		08-2022	08-2022	08-2022
Date of Initiation		27-08-2022	27-08-2022	27-08-2022
No. of Batches		03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. (189/2022-DRAP(AD-99778029213) dated 22/10/2022 issued by Drug Regulatory Authority of Pakistan. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 20-07-2022 specifying 18.5000Kg of clarithromycin. The invoice is cleared by dawn Shaigan Pharmaceuticals Pvt. Ltd.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		

Remarks of Evaluator:

Under 1.6.5 (a) you have mentioned M/s Surge Laboratories (Pvt) Limited, Pakistan as API manufacturer, however as per record the aforesaid manufacturer is manufacturing bulk Clarithromycin Granules. You are hereby advised to submit the name and address of API manufacturer rather source of half finished product manufacturer.

Under 1.6.5 (b) the approval of manufacturing facility of Clarithromycin API is required rather bulk Clarithromycin Granules.

The drug substance i.e., Clarithromycin API information need to be submitted under 2.3.S and 3.2.S as required under DRAP guidance document.

The manufacturing of Clarithromycin taste masked granules needs to be included in the Drug Product Modules being the part of drug product manufacturing.

The following information need to be submitted by M/s Surge Laboratories (Private) Limited Pakistan, 10th KM, Faisalabad Road Bikhi, District Sheikhupura:

a. Copies of DRAP attested invoices for purchase of Clarithromycin API along with Certificate of analysis.
b. Composition of Clarithromycin granules needs to be submitted in table format indicating quantities per dosage unit and function of each excipient with its reference to standard.
c. Overages added or not.
d. Description of container closure system.

e. Name of the reference/ branded product keeping in view the generic taste masked pellets have been developed.
f. Justification that the choice excipients is in line with the reference/ innovator product. In case different excipients have been used then justify and submit compatibility studies as well.
g. Optimization studies (if any) for confirming final the quantities of excipients.
h. Pharmaceutical equivalence studies.
i. Comparative dissolution studies in physiological media.
j. Manufacturing process development data along with the explanation of manufacturing enteric coated granules. This should be justified with experimental data or with reference literature which indicates that clarithromycin is degradable in gastric pH/ medium. The data of initial trails conducted (wherein 5:3 ratio uncoated granules were good for coating) will be valuable document for review.
k. Commercial batch formula with quantities of raw materials used.
l. Manufacturing process flow chart indicating input materials and In-process test.
m. Process qualification protocol and process performance qualification report with results of three commercial scale batches.
n. Under specifcations, justification is required for mentioning pH limits 3.5-7.0, however USP limits are 4.0-5.4.
o. Justification for dissolution specifcations for granules in two media and their limits.
p. Justification for assigning LOD specifications NMT 5% however as per pharmacopeia the specs are NMT 2%. Clarification is also required that in the manufacturing process at step: Drying and Unloading of Coated Granules of Clarithromycin you are drying the granules at 45-55^{0}C till to get LOD NMT 2% however the specs are assigned NMT 5%.
q. Justification for conducting heavy metals test.
r. Justification for not specifying the tests for impurities in specifcations.
s. Clarification required as Class III solvents are being used in the manufacturing process however their residual limits are not specified in the final specifcations.
t. Copies of monographs of the excipients as per pharmacopeial reference mentioned in dossier
u. Certificate of analysis of reference standards.
v. Evidence of availability of Gas Chromatograph for testing benzene in Acrypol 934 and EG/PEG in PEG 6000 and other quality tests required testing using Gas Chromatograph of other excipients.
w. Details of PEG batches recently purchased/ imported and tested for DEG/EG impurities in compliance to DRAP directives. CoA need to submitted as evidence.
x. Copy of approval of quota allocation from Control Drugs Division of DRAP for import/ purchase of acetone for batch No. K3587937 Mfg Date 08-2018 and Exp date 12-2022 GRN No: 19120035.
y. Stress testing study data as the API has been exposed to 80^{o}C during the manufacturing process form almost 10-12 hours for two times and also at 45-55^{0}C for attaining the desired moisture Limits
z. Justification for conducting tests for LOD and impurities in the stability testing.
aa. Stability data of last three batches under ongoing stability program.

Copy of the invoice of purchase of 18.5Kg of clarithromycin granules.

3.2. P.1 Justification for adding Citric acid and titanium dioxide in the in the formulation as the granules manufacturer has already added the same in the formulation. Moreover, the composition of plastic bottle along with description and composition of cap needs to be elaborated.

3.2. P.2 Justify that the composition of applied formulation is same as of Innovator/ reference product.

3.2.P.2.2.1 Details of the batch (Batch No., Mfg and expiry) of the reference product used for pharmaceutical equivalence and comparative dissolution.

Justification for adding the microbiological enumeration tests and tests for specified microorganisms in in pharmaceutical equivalence studies.

Details of the results on the suggested time points of dissolution of 12 units of innovator and test product with batch No. in a table format of three physiological media for CDP as the submitted details are insufficient and only at 6.8 pH (3.2.P.2.2.1)

3.2.P.4 Reference of specifcations for control of excipients.

3.2.P.5. Justify specification limits of LOD as the manufacturer providing the granules has limits NMT 5%. and limits for pH 3.5-7.0.

The Certificate of analysis generated by you vide No. 14650 dated 23.07.2022 has LOD 2.23% for Batch (CTM-1-663) of Clarithromycin granules supplied by the source used for manufacturing of product. Please clarify how the LOD was reported less than 2% in the finished product.

The Certificate of analysis generated by you vide No. 14650 dated 23.07.2022 reported pH 6.08 for Batch (CTM-1-663) of Clarithromycin granules supplied by the source used for manufacturing of product. Please clarify how the pH was reported within 4-5.4 for three batches of finished product. Certificate of analysis of reference standards submitted under 3.2. P.6. Justification that quantity per batch is justified w.r.t the tests needed to perform stability for proposed shelf life.		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings		
570.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Pvt. Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals Pvt. Ltd. 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-12-2021/ based on inspection conducted on 24/11/2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 13-01-2022 specifying Oral Dry Powder Suspension new
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No…. dated 29/03/2023
	Details of fee submitted	PKR 30,000/- Dated 18/01/2023
	The proposed proprietary name / brand name	**Azitrax 200mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Azithromycin(as dihydrate)……200mg
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotics
	Pharmaceutical form of applied drug	oral suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	1's 30ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zithromax 200mg/5ml Dry Suspension new York United State
	For generic drugs (me-too status)	Zetamax Dry Suspension Pfizer Pakistan Limited
	Name and address of API manufacturer.	Hebei Guolong Pharmaceutical Co.,Ltd. No. 9 Xingye street, Shijiazhuang Economic and Technological Development Zone, Hebei Province
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general

		properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Zetamax 200mg/5ml Dry Suspension Suspension manufactured by Pfizer Pakistan Limited Firm has submitted CDP results of their product against the innovator's product Zetamax 200mg/5ml Dry Suspension in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Hebei Guolong Pharmaceutical Co.,Ltd.		
API Lot No.	211207010		
Description of Pack (Container closure system)	Amber Colored Bottle		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	11-08-2022	11-08-2022	11-08-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (HE20190147) dated 22/10/2019 issued by CHINA food and Drugs Administration CHINA. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 11-05-2020 specifying 500Kg of azithromycin Dihydrate . The invoice is cleared by dawn Impex Karachi bank al Habib Limited Karachi
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

571.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals Pvt Ltd, 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-12-2021/ based on inspection conducted on 24/11/2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 13-01-2022 specifying sachet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8952 dated 03.04.2023
	Details of fee submitted	PKR 30,000/- Dated 03-04-2023

	The proposed proprietary name / brand name	**ASETIN 200MG SACHET**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Acetylcysteine…...200mg
	Pharmacotherapeutic Group of (API)	mucolytic agents
	Pharmaceutical form of applied drug	Powder for oral suspension
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	16's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Acetylcysteine 200 mg Powder for Oral Solution Italy
	For generic drugs (me-too status)	Mucolator 200mg sachet Abbott Laboratories (Pakistan) Ltd.
	Name and address of API manufacturer.	M/s Wuhan Grand Hoyo Co, Ltd., No. 1 Industrial Park Gedian Economy Development Zone, Ezhou City, Hubei Province China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Mucolator 200mg sachet, manufactured by Abbott Laboratories United Kingdom Firm has submitted CDP results of their product against the innovator's product Mucolator 200mg sachet, in 3 dissolution medias.

	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Wuhan Grand Hoyo Co, Ltd., No. 1 Industrial Park Gedian Economy Development Zone, Ezhou City, Hubei Province China		
API Lot No.		S202205027		
Description of Pack (Container closure system)		Aluminium Sachet		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T-055NS02	Batch No.	T-055NS02
Batch Size		500 Sachet	Batch Size	500 Sachet
Manufacturing Date		07-2022	Manufacturing Date	07-2022
Date of Initiation		22-06-2022	Date of Initiation	22-06-2022
No. of Batches		03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. HB20190479) dated 04-03-2019 issued by Food and Drugs Control Administration CHINA. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on MAY 23'2022 specifying 500g of Acetylcysteine. The invoice is cleared by Wuhan Grand Hoyo Co, Ltd		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
Remarks of Evaluator:				
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**				
New Section Applications:				

M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa-Pakistan was granted addition section Cream/ Ointment/ Gel section (general) on 9.4.2020. Accordingly following products are placed for consideration:		
572.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa-Pakistan**
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Limited P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate # F.11-6/2021-DRAP-65, dated 25-08-2021 based on inspection conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Ointment/Cream Section (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 3-14/2004-Lic (Vol-I), dated: 26-10-2020.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24.05.2023
	Details of fee submitted	PKR 30,000/- Slip# 9709041254, Dated 16-03-2023
	The proposed proprietary name / brand name	**TERF CREAM 1%**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gm contains: Terbinafine hydrochloride….10mg
	Pharmacotherapeutic Group of (API)	Antifungal for topical use
	Pharmaceutical form of applied drug	White homogenous cream
	Reference to Finished product specifications	JP Specifications
	Proposed Pack size	5g, 10g, 15g, 30g, 50g
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lamisil Cream 1% (Approved BY FDA)
	For generic drugs (me-too status)	Terbimax Cream 1% (M/s Maxitech Pharma (Pvt) Ltd.)
	Name and address of API manufacturer.	Zhejiang East-Asia Pharmaceutical Co., Ltd Address: Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China.317100
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Terbinafine HCl is B.P., the firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance Terbinafine HCl at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batches: (DC-013-1707001, DC-013-1707002, DC-013-1707003)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Innovator product Lamisil Cream 1% manufactured by M/s GSK.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Terbinafine HCl:** M/s Zhejiang East-Asia Pharmaceutical Co., Ltd Address: Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China. 317100		
API Lot No.	DC-013-2106003		
Description of Pack (Container closure system)	Collapsible Alu-Tube packed in a unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	174NS04	174NS05	174NS06
Batch Size	3000 grams	3000 grams	3000 grams
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation of stability studies	20-04-2022	20-04-2022	20-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Hexigard Gel, for which the inspection was conducted on 26-07-2019 and the report was presented in 291st meeting of Registration Board. The report confirms following points: ix. The HPLC software is 21CFR compliant. x. Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Written Confirmation issued dated 14-11-2022 valid up to 13-11-2025 issued by Zhejiang Medical Products Administration.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 # 00977/2021-DRAP(P)/3554 dated on 14-09-2021 specifying 0.585kg. The Form 6 is cleared by AD (I&E) DRAP, Peshawar.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Deputy Director (PEC) (Mr. Salateen Waseem Philip)

Item No. 01: Routine cases

573.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WeatherFolds Pharmaceuticals (DML # 000644) Plot No. 62/2 Phase-II Industrial Estate Hattar.**
	Name, address of Manufacturing site.	M/s WeatherFolds Pharmaceuticals (DML # 000644) Plot No. 62/2 Phase-II Industrial Estate Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate valid up to: 27-10-2025
	Evidence of approval of manufacturing facility	Tablet (General) Section, Approval by Central Licensing Board in its 222nd meeting held on 04th March 2010.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23666 dated 24-08-2022
	Details of fee submitted	PKR 30,000/-: Dated 23-06-2022 Slip # 09661966934
	The proposed proprietary name / brand name	AXNAP 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apixaban ……. 5 mg
	Pharmaco-therapeutic Group of (API)	Factor Xa (FXa) inhibitor
	Pharmaceutical form of applied drug	Film coated tablets
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ELIQUIS® by Bristol-Myers Squibb Company USA USFDA approved formulation
	For generic drugs (me-too status)	**Brand Name:** Abaxil 5mg Tablet. **Manufacturer:** M/s Saffron
	Name and address of API manufacturer.	Name: M/s Changzhou Pharmaceutical Factory Address: Laodong E Rd, Tianning District, Changzhou, Jiangsu, China. GMP validity : 24-09-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and

		stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Elixaban 5 mg Tablet **Manufactured by:** Martin Dow **Testing Parameters:** Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: M/s Changzhou Pharmaceutical Factory Address: Laodong E Rd, Tianning District, Changzhou, Jiangsu, China.		
API Lot No.	ZSAP210401		
Description of Pack (Container closure system)	ALU-ALU Blisters of 3 x 10's further packed in Bleach Card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	Trial-03	Trial-04	Trial-05
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	30-07-2021	30-07-2021	30-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form 6 issuance date: 02-07-2021 Quantity: 0.1 kg License No: 00692/2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved with Innovator's specifications.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
574.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WeatherFolds Pharmaceuticals (DML # 000644)** **Plot No. 62/2 Phase-II Industrial Estate Hattar.**
	Name, address of Manufacturing site.	M/s WeatherFolds Pharmaceuticals (DML # 000644) Plot No. 62/2 Phase-II Industrial Estate Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24969 (dated: 02-09-2022)
	Details of fee submitted	PKR 30,000/-: dated: 22-08-2022 (Invoice # 258804401)
	The proposed proprietary name / brand name	Vonp-AS 10/100 Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Aspirin as Enteric Coated Tablet …... 100 mg **With drug coating of** Vonoprazan as fumarate as immediate release layer …… 10 mg
	Pharmaceutical form of applied drug	Yellow color round in shape, film coated tablets (Aspirin delayed release and Vonoprazan immediate release tablets)
	Pharmacotherapeutic Group of (API)	NSAID + Potassium competitive Acid Blocker
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PMDA approved **Cabpirin ®** by Otsuka.
	For generic drugs (me-too status)	N/A
	Section Approval Letter from Licensing Division of DRAP	Tablet (General) Section, Approval by Central Licensing Board in its 222nd meeting held on 04th March 2010.
	GMP status of the Finished product manufacturer	GMP certificate valid up to: 27-10-2025
	Name and address of API manufacturer.	**Vonprazan** **Name:** M/s AMI Life Sciences **Address:** Block No.82/B, ECP Road, At & Post. Karakhadi-391450 Taluka: Padra Dist.: Vadodara Gujarat, INDIA. **GMP Validity:** expired in year 2022

		Aspirin **Name:** M/s JQC (HUAYIN) Pharmaceutical Co. Ltd. **Address:** Yuquan Road, Huayin City, Shanxi Province, China. **GMP Validity:** expired in year 2022
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	**Vonoprazan** Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 12 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months **Aspirin** Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 48 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Cabpirin 100/10 Tablet **Manufacturer:** M/s Otsuka **Testing parameters:** Innovator Specifications **Batch #** 521559
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.
STABILITY STUDY DATA		
Manufacturer of API		**Vonprazan** **Name:** M/s AMI Life Sciences **Address:** Block No.82/B, ECP Road, At & Post. Karakhadi-391450 Taluka: Padra Dist.: Vadodara Gujarat, INDIA. **GMP Validity:** expired in year 2022 **Aspirin** **Name:** M/s JQC (HUAYIN) Pharmaceutical Co. Ltd. **Address:** Yuquan Road, Huayin City, Shanxi Province, China.

	GMP Validity: expired in year 2022		
API Lot No.	**Vonoprazan fumarate**	**Aspirin**	
	Not provided	Not provided	
Description of Pack (Container closure system)	30 in ALU-ALU Blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	21-09-2021	21-09-2021	21-09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 100 kg **Invoice #** 2122/SL/032 **Dated:** 05-08-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Reply of the firm
1.6.5	• Please submit GMP Certificate of API suppliers for Vonoprazan and Aspirin which should be in force till date.	Submitted
3.2.P.2	• Please justify that why drug coating method of tablet has been chosen instead of bilayer tablets which is a recommended method for tablet formulation for combination of two incompatible APIs?	As one salt is enteric coated and other is immediate release so we chose drug coating method. The same formulation has been already approved by DRB.
	• Please submit evidence that innovator brand "Cabpirin combination tablet" by Otsuka,	Firm has submitted PMDA JAPAN approval.

	Japan, is a vonoprazan coated tablet and not a bilayer tablet of two APIs.	
	• Since Vonoprazan has a bitter taste, what steps have been taken to mask the bitter taste of API coating?	The formulation is in tablet dosage form and the dual coating will prevent the bitter taste.
	• Please clarify whether in process test for Vonoprazan containing drug coating suspension has been performed? If yes, then submit validation data as well as analytical testing parameters with reference of testing.	Report submitted
	• Please submit data regarding weight gain of enteric coated tablet of Aspirin before and after spraying the drug coating suspension containing Vonoprazan.	Master formulation along with weight gains at each step Submitted
	• Please submit documented evidence that the coating machine used for drug coating suspension contains Human machine interface (HMI) to control the opening and closing of the exhaust during coating time.	Automatic exhaust system in lab scale coating pan
3.2.P.5	• Please submit detailed procedure regarding disintegration time requirement for drug coating of vonoprazan and then disintegrating time of enteric coated aspirin.	Submitted
	• Please submit detailed dissolution procedure along with reference.	Submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

575.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welwrd Pharmaceuticals (DML # 000574)** **Plot No. 03, Block A, Phase-I & II, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Welwrd Pharmaceuticals (DML # 000574) Plot No. 03, Block A, Phase-I & II, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate valid up to: 29-03-2024
	Evidence of approval of manufacturing facility	Approval of renewal of DML including Injection Ampoule / Vial (General), in 247th meeting of Central Licensing Board held on 29th April 2016.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27129 dated 26-09-2022
	Details of fee submitted	PKR 30,000/-: Dated 01-02-2022 Slip # 1762226824
	The proposed proprietary name /	Welsetron Injection 4mg

	brand name	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml vial contains: Ondansetron ……. 4 mg
	Pharmaco-therapeutic Group of (API)	Serotonin (5HT3) antagonist
	Pharmaceutical form of applied drug	Film coated tablets
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2 ml vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved Zofran ® Injection.
	For generic drugs (me-too status)	**Brand Name:** Ondanz Injection 4mg **Manufacturer:** M/s Welwink
	Name and address of API manufacturer.	Name: M/s Shodhana Laboratories Limited. Address: Plot # 24,25,26, IDA, Phase I, Jeedimetla, Hyderabad, Telangana, India. GMP validity : compliant
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** Ondanz Injection 4mg **Manufacturer:** M/s Welwink **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: M/s Changzhou Pharmaceutical Factory Address: Laodong E Rd, Tianning District, Changzhou, Jiangsu, China.		
API Lot No.	***Not provided***		
Description of Pack (Container closure system)	Glass Ampoules		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	A001	A002	A003
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	01-10-2020	01-10-2020	01-10-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	• Please submit the GMP certificate of API manufacturer issued by Regulatory Authority of Country of Origin and should be inforce till date.	Submitted
3.2.P.2	• Please justify that Pharmaceutical equivalence studies have been performed with a local brand instead of innovator brand /brand leader?	As per WHO guidelines.
3.2.P.5	• Please re-check the limits of specifications submitted vs specification claimed.	Correction done
3.2.P.7	• Please submit details of this section.	Submitted
3.2.P.8	• Please submit DRAP clearance for the API import.	Submitted
	• Please submit COA of API used in product development and manufacturing of stability batches.	Submitted
	• Please submit calculation sheets for analysis results of HPLC of all stability batches for both accelerated and long term studies. Calculation sheets should	Submitted

	fulfil all the parameter required to properly represent the weights in mg/gm, dilutions, formula used etc.	

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

576.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Valor Pharmaceuticals (DML # 000496)** **Plot No. 124-A, Industrial Triangle, Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Valor Pharmaceuticals (DML # 000496) Plot No. 124-A, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Central Licensing Board in its 180th meeting held on 03rd & 4th September 2003 approved the additional section "Tablet (Quninolone)."
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22877 dated 12-08-2022
	Details of fee submitted	PKR 30,000/-: Dated 22-06-2022 Slip # 308874171
	The proposed proprietary name / brand name	Atorval 20 mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Atorvastatin calcium (as tri-hydrate) equivalent to Atorvastatin ……. 20 mg
	Pharmaco-therapeutic Group of (API)	Lipid modifying agents, HMG-CoA-reductase inhibitors.
	Pharmaceutical form of applied drug	Film coated tablets
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 10s per unit pack.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved Lipitor® Tablet 20mg.
	For generic drugs (me-too status)	**Brand Name:** Lipiget 20mg Tablet **Manufacturer:** M/s Getz Pharma
	Name and address of API manufacturer.	Name: M/s Ind-swift Laboratories Limited. Address: Vill. Bhagwanpur, Barwala Road, Near Dera Bassi, Distt. S.A.S Nagar (Mohali), Punjab, India.

		GMP validity : **31-12-2022**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 48 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** Lipiget 20 mg Tablet **Manufacturer:** M/s Getz Pharma **Testing Parameters:** USP Parameters **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: M/s Ind-swift Laboratories Limited. Address: Vill. Bhagwanpur, Barwala Road, Near Dera Bassi, Distt. S.A.S Nagar (Mohali), Punjab, India.		
API Lot No.	L421010026		
Description of Pack (Container closure system)	ALU-ALU Blisters		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-019	T-020	T-021
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets

Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	01-01-2022	01-01-2022	01-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.3.4	• For the manufacturing facility of Tablet (General) Section, please submit the evidence of section approval in the meeting of Central Licensing Board.	Submitted
	• Please submit fresh / valid GMP certificate issued by DRAP OR inspection report conducted within last three years.	*Not yet submitted*
1.6.5	• Please submit the GMP certificate of API manufacturer issued by Regulatory Authority of Country of Origin and should be inforce till date.	Expired on 31-12-2022
3.2.P.8	• Please submit DRAP clearance documents for API import.	Submitted

Decision: Approved. The registration letter shall be issued after submission of latest GMP inspection report of drug product manufacturer conducted within last three years.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

577.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Davis Pharmaceutical Laboratories (DML # 000432) Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	**M/s Davis Pharmaceutical Laboratories (DML # 000432) Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate valid up to: 01-02-2024
	Evidence of approval of manufacturing facility	Central Licensing Board in its 241st meeting held on 15th May 2015 approved the renewal of DML of the firm including Tablet (General) Section.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23672 dated 22-08-2022
	Details of fee submitted	PKR 30,000/-: Dated 31-05-2022 Slip # 6870942629
	The proposed proprietary name / brand name	**Rivo 10 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Rivaroxaban ……...……10mg
	Pharmaco-therapeutic Group of (API)	Antithrombotic agents ATC code: B01AF01
	Pharmaceutical form of applied drug	Film coated tablets
	Reference to Finished product specifications	Manufacturer Specifications
	Proposed Pack size	4 x 7s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XARELTO®, a USFDA approved formulation.
	For generic drugs (me-too status)	Brand Name: Revaxo 10mg Tablet Manufacturer: M/s Getz Pharma
	Name and address of API manufacturer.	Name: M/s Zhejiang Tianyu Pharmaceutical Co. Ltd. Address: Jiangkou Development Zone, Huangyan, Taizhou City, China. GMP validity : **14-03-2023**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 12 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture,

		manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** Rivaxo 10 mg Tablet **Manufacturer:** M/s Getz Pharma **Testing Parameters:** Manufacturer Parameters **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: M/s Zhejiang Tianyu Pharmaceutical Co. Ltd. Address: Jiangkou Development Zone, Huangyan, Taizhou City, China.		
API Lot No.			
Description of Pack (Container closure system)	ALU-ALU Blisters		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-021	T-022	T-023
Batch Size	4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	03-2021	03-2021	03-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	***Not provided***
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity

		monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations
1.5.6	• Please justify that why Manufacturer Specification should be accepted when monograph is available in BP Pharmacopeia? • Please submit evidence as per ICH guidelines that Manufacturer specifications are more stringent than the specification of this formulation available in BP Pharmacopeia.
1.6.5	• Please submit the GMP certificate of API manufacturer issued by Regulatory Authority of Country of Origin and should be inforce till date.
3.2.P.2	• Please justify that why Lactose monohydrate & Sodium Lauryl sulfate are not part of your formulation while the same ingredients in innovator formulation contributes in CQAs?
3.2.P.2.2	• Please justify that why testing parameters of BP specifications have not been adopted? • Please submit evidence as per ICH guidelines that Manufacturer specifications are more stringent than the specification of this formulation available in BP Pharmacopeia. Please provide reference of the method and limits for dissolution test.
3.2.P.5	• Please justify that why Manufacturer Specification should be accepted when monograph is available in BP Pharmacopeia? • Please submit evidence as per ICH guidelines that Manufacturer specifications are more stringent than the specification of this formulation available in BP Pharmacopeia.
3.2.P.8	• Please submit DRAP clearance documents for API import. • Please submit COA of API LOT # used in manufacturing of stability batches. • Please submit reference of analytical method of dissolution. • Please submit complete set of chromatograms for each interval of testing along with calculation sheets. Calculation sheets should have essential parameter such as weight in mg/gm, dilutions, formula etc.

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

578.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Davis Pharmaceutical Laboratories (DML # 000432) Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	**M/s Davis Pharmaceutical Laboratories (DML # 000432) Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate valid up to: 01-02-2024
	Evidence of approval of manufacturing facility	Central Licensing Board in its 241st meeting held on 15th May 2015 approved the renewal of DML of the firm including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23671 dated 22-08-2022
	Details of fee submitted	PKR 30,000/-: Dated 31-05-2022 Slip # 03281486508
	The proposed proprietary name / brand name	Rivo 15 mg Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Rivaroxaban ……...……15 mg
	Pharmaco-therapeutic Group of (API)	Antithrombotic agents ATC code: B01AF01
	Pharmaceutical form of applied drug	Film coated tablets
	Reference to Finished product specifications	Manufacturer Specifications
	Proposed Pack size	4 x 7s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XARELTO®, a USFDA approved formulation.
	For generic drugs (me-too status)	Brand Name: Revaxo 15mg Tablet Manufacturer: M/s Getz Pharma
	Name and address of API manufacturer.	Name: M/s Zhejiang Tianyu Pharmaceutical Co. Ltd. Address: Jiangkou Development Zone, Huangyan, Taizhou City, China. GMP validity : **14-03-2023**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 12 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** Rivaxo 15 mg Tablet **Manufacturer:** M/s Getz Pharma **Testing Parameters:** Manufacturer Parameters **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.

	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: M/s Zhejiang Tianyu Pharmaceutical Co. Ltd. Address: Jiangkou Development Zone, Huangyan, Taizhou City, China.		
API Lot No.			
Description of Pack (Container closure system)	ALU-ALU Blisters		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-024	T-025	T-026
Batch Size	4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	04-2021	04-2021	04-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	***Not provided***
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations
1.5.6	• Please justify that why Manufacturer Specification should be accepted when monograph is available in BP Pharmacopeia? • Please submit evidence as per ICH guidelines that Manufacturer specifications are more stringent than the specification of this formulation available in BP Pharmacopeia.
1.6.5	• Please submit the GMP certificate of API manufacturer issued by Regulatory Authority of Country of Origin and should be inforce till date.
3.2.P.2	• Please justify that why Lactose monohydrate & Sodium Lauryl sulfate are not part of your formulation while the same ingredients in innovator formulation contributes in CQAs?
3.2.P.2.2	• Please justify that why testing parameters of BP specifications have not been adopted?

	• Please submit evidence as per ICH guidelines that Manufacturer specifications are more stringent than the specification of this formulation available in BP Pharmacopeia. Please provide reference of the method and limits for dissolution test.
3.2.P.5	• Please justify that why Manufacturer Specification should be accepted when monograph is available in BP Pharmacopeia? • Please submit evidence as per ICH guidelines that Manufacturer specifications are more stringent than the specification of this formulation available in BP Pharmacopeia.
3.2.P.8	• Please submit DRAP clearance documents for API import. • Please submit COA of API LOT # used in manufacturing of stability batches. • Please submit reference of analytical method of dissolution. • Please submit complete set of chromatograms for each interval of testing along with calculation sheets. Calculation sheets should have essential parameter such as weight in mg/gm, dilutions, formula etc.

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

579.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Davis Pharmaceutical Laboratories (DML # 000432) Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	**M/s Davis Pharmaceutical Laboratories (DML # 000432) Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate valid up to: 01-02-2024
	Evidence of approval of manufacturing facility	Central Licensing Board in its 241st meeting held on 15th May 2015 approved the renewal of DML of the firm including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23673 dated 22-08-2022
	Details of fee submitted	PKR 30,000/-: Dated 31-05-2022 Slip # 928723210
	The proposed proprietary name / brand name	**Rivo 20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Rivaroxaban ……...……20 mg
	Pharmaco-therapeutic Group of (API)	Antithrombotic agents ATC code: B01AF01
	Pharmaceutical form of applied drug	Film coated tablets
	Reference to Finished product specifications	Manufacturer Specifications
	Proposed Pack size	4 x 7s
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	XARELTO®, a USFDA approved formulation.
	For generic drugs (me-too status)	Brand Name: Revaxo 20 mg Tablet Manufacturer: M/s Getz Pharma
	Name and address of API manufacturer.	Name: M/s Zhejiang Tianyu Pharmaceutical Co. Ltd. Address: Jiangkou Development Zone, Huangyan, Taizhou City, China. GMP validity : **14-03-2023**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 12 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** Rivaxo 20 mg Tablet **Manufacturer:** M/s Getz Pharma **Testing Parameters:** Manufacturer Parameters **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Name: M/s Zhejiang Tianyu Pharmaceutical Co. Ltd. Address: Jiangkou Development Zone, Huangyan, Taizhou City, China.
API Lot No.	
Description of Pack (Container closure system)	ALU-ALU Blisters
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-027	T-028	T-029
Batch Size	4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	05-2021	05-2021	05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	***Not provided***
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations
1.5.6	• Please justify that why Manufacturer Specification should be accepted when monograph is available in BP Pharmacopeia? • Please submit evidence as per ICH guidelines that Manufacturer specifications are more stringent than the specification of this formulation available in BP Pharmacopeia.
1.6.5	• Please submit the GMP certificate of API manufacturer issued by Regulatory Authority of Country of Origin and should be inforce till date.
3.2.P.2	• Please justify that why Lactose monohydrate & Sodium Lauryl sulfate are not part of your formulation while the same ingredients in innovator formulation contributes in CQAs?
3.2.P.2.2	• Please justify that why testing parameters of BP specifications have not been adopted? • Please submit evidence as per ICH guidelines that Manufacturer specifications are more stringent than the specification of this formulation available in BP Pharmacopeia. Please provide reference of the method and limits for dissolution test.
3.2.P.5	• Please justify that why Manufacturer Specification should be accepted when monograph is available in BP Pharmacopeia? • Please submit evidence as per ICH guidelines that Manufacturer specifications are more stringent than the specification of this formulation available in BP Pharmacopeia.
3.2.P.8	• Please submit DRAP clearance documents for API import. • Please submit COA of API LOT # used in manufacturing of stability batches. • Please submit reference of analytical method of dissolution. • Please submit complete set of chromatograms for each interval of testing along with calculation sheets. Calculation sheets should have essential parameter such as weight in mg/gm, dilutions, formula etc.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
580.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Venus Pharma (DML # 000300)** **23-km, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Venus Pharma (DML # 000300) 23-km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate valid up to: 13-09-2025
	Evidence of approval of manufacturing facility	Not provided
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27407 dated 27-09-2022
	Details of fee submitted	PKR 30,000/-: Dated 31-05-2022 Slip # 125635671
	The proposed proprietary name / brand name	**Cyanocobalamin Injection 2cc**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml contains: Cyanocobalamin ……...……500 mcg
	Pharmaco-therapeutic Group of (API)	Cyanocobalamin
	Pharmaceutical form of applied drug	IM Injection
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	2ml x 25's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not available
	For generic drugs (me-too status)	**Brand Name:** Cyanocobalamin Injection 2cc **Manufacturer:** M/s Ameer Pharma. **Reg.** # 049054. **Brand Name:** Adcyna Injection 500mcg/2ml **Manufcaturer:** Ameer & Adnan Pharmaceuticals (Pvt) Ltd., 47 Sundar Industrial Estate Lahore, Lahore. **Reg.** # 78924.
	Name and address of API manufacturer.	Name: M/s YUXING Biotechnology (Group) Co. Ltd. Address: XiCheng District, Ningjin County, Bebei Province, China. GMP validity : 29-11-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure,

		general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** Cyanocobalamin Injection **Manufacturer:** M/s Ameer Pharma **Testing Parameters:** USP specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA		
Manufacturer of API	Name: M/s YUXING Biotechnology (Group) Co. Ltd. Address: XiCheng District, Ningjin County, Bebei Province, China.	
API Lot No.	C210720D	
Description of Pack (Container closure system)	Clear Glass Ampoules	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period	Real time: 06 months Accelerated: 06 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)	
Batch No.	CTD-02	CTD-04
Batch Size	4.2 L	4.2 L
Manufacturing Date	10/2021	10/2021
Date of Initiation	25-10-2021	25-10-2021
No. of Batches	02	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 5kg **Dated:** 27-08-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	UV spectroscopy
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.3.4	• Please submit valid / fresh GMP certificate of your firm issued by DRAP OR inspection report conducted within last three years for confirmation of GMP compliance status of the manufacturing facility.	Submitted
	• For the manufacturing facility of Liquid Injectable (vials & ampoules – General Section), please submit evidence of Section approval in the meeting of Central Licensing Board.	Firm submitted the renewal of DML mentioning the section.
1.5.9	• Please submit evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	In RRA (USFDA & ANSM), the formulation is available in 1000mcg/ml. but firm requested to consider their formulation of 500 mcg/2ml on the basis of vitamin policy.
1.6.5	• Please submit the GMP certificate of API manufacturer issued by Regulatory Authority of Country of Origin and should be inforce till date.	Submitted
3.2.P.8	• Please submit DRAP clearance documents for API import.	Submitted
	• Please submit details of three stability batches such as manufacturing date, batch size, date of initiating testing, API Lot#.	Submitted

Decision: Deferred for the evidence of RRA

581.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s News Pharma (DML # 000775)** **Plot # 42, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s News Pharma (DML # 000775) Plot # 42, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection report dated 28-07-2021 for grant of new section Oral Liquid General Section.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 283rd meeting held on 28th October 2021 approved the grant of additional section Oral Liquid (General) Section.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27408 dated 27-09-2022
	Details of fee submitted	PKR 30,000/-: Dated 19-09-2022 Slip # 9461559852
	The proposed proprietary name / brand name	New-Set 4mg/5ml Syrup
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml of liquid syrup contains: Ondansetron $HCl.2H_2O$ equivalent to Ondansetron ……...……4 mg
	Pharmaco-therapeutic Group of (API)	5-HT3 antagonist
	Pharmaceutical form of applied drug	Oral Liquid Syrup
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	30ML, 60 ML
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran® 4mg/5ml, MHRA approved formulation.
	For generic drugs (me-too status)	Brand Name: Dantron 4mg/5ml Manufacturer: M/s Shrooq Pharma
	Name and address of API manufacturer.	Name: M/s Anugraha Chemicals Research & Development Address: No. D-47 to D-50, C-62 & C-63, KSSIDC Industrial Estate, Doddaballapur, Banglore, Karnataka, India. GMP validity : 09-04-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product,

		specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** Onseron 4 mg/ 5ml Syrup **Manufacturer:** M/s Indus Pharma **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: M/s Anugraha Chemicals Research & Development Address: No. D-47 to D-50, C-62 & C-63, KSSIDC Industrial Estate, Doddaballapur, Banglore, Karnataka, India.		
API Lot No.	AOND-22005		
Description of Pack (Container closure system)	Amber colored 60ml glass bottles packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	11-2021	11-2021	11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Quanity:5kg Dated: 11-09-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	• Please submit the GMP certificate of API manufacturer issued by Regulatory Authority of Country of Origin and should be inforce till date.	Submitted

3.2.P.8	• Please submit DRAP clearance documents for API import. • Please submit COA of API LOT # used in manufacturing of stability batches. • Please submit calculation sheets which should have essential parameter such as weight in mg/gm of sample & standards, dilutions, formula of calculation as per USP Specifications etc.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

582.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Inventor Pharma (DML # 000866)** **Plot # K/196, S.I.T.E. (SHW) Phase-II, Karachi.**
	Name, address of Manufacturing site.	M/s Inventor Pharma (DML # 000866) Plot # K/196, S.I.T.E. (SHW) Phase-II, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate validity: ***expired on 19-09-2021***
	Evidence of approval of manufacturing facility	Central Licensing Board in its 254th meeting held on 15th June 2017 approved the grant of DML including Oral Liquid (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23961 dated 24-08-2022
	Details of fee submitted	PKR 30,000/-: Dated 09-05-2022 Slip # 561406819
	The proposed proprietary name / brand name	INDEON Syrup 4mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml of liquid syrup contains: Ondansetron $HCl.2H_2O$ equivalent to Ondansetron ……...……4 mg
	Pharmaco-therapeutic Group of (API)	5-HT3 antagonist
	Pharmaceutical form of applied drug	Oral Liquid Syrup
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	60 ML
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran® 4mg/5ml, MHRA approved formulation.
	For generic drugs (me-too status)	Brand Name: Onseron 4mg/5ml Manufacturer: M/s Indus Pharma

	Name and address of API manufacturer.	Name: M/s Cipla – Kurkumbh Cipla Limited. Address: No. D-22, MIDC Industrial Area, Kurkumbh Village, Taluka-Daund, District-Pune (Maharashtra), India. GMP validity : ***not provided***
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** Onseron 4 mg/ 5ml Syrup **Manufacturer:** M/s Indus Pharma **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: M/s Anugraha Chemicals Research & Development Address: No. D-47 to D-50, C-62 & C-63, KSSIDC Industrial Estate, Doddaballapur, Banglore, Karnataka, India.		
API Lot No.	01701012106001		
Description of Pack (Container closure system)	Amber colored 60ml glass bottles packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	11-2021	11-2021	11-2021

Date of Initiation	11-2021	11-2021	11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	***Not provided***
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations
1.6.5	• Please submit the GMP certificate of API manufacturer issued by Regulatory Authority of Country of Origin and should be inforce till date.
3.2.P.1	• Please clarify that how 48mg/5ml of Ondansetron HCl in the composition of your product represent 4mg / 5ml of Ondansetron in your label claim? • Please submit evidence of approval of your formulation in reference regulatory authorities which contains xanthan gum as an excipient in the oral solution formulation. • Please justify the role of methyl paraben and propyl paraben in your formulation when sodium benzoate is also present in your formulation as preservative. • Please mention the amount of ethanol in your formulation due to Sorbitol L.
3.2.P.2	• Please justify that why Pharmaceutical equivalence studies have been performed against a local brand instead of brand leader / Innovator brand? • Please clarify that why assay limits for ondansetron in your formulation are 90% to 110% for drug product while USP specification provide assay limits for ondansetron in drug product are 95% to 105%? • Please justify that why limits of pH for drug product mentioned as 3.6 – 4.6 while the USP specification claimed contains limits of pH as 3.3 -4.0?
3.2.P.5	• Please clarify that why composition of mobile phase is different from the composition of mobile phase provided in USP pharmacopeia? • Please clarify that why calculation formula mentioned in your CTD is different from the calculation formula given in USP specifications?
3.2.P.6 to 3.2.P.7	• Please submit the documents /information of these sections as missing in the dossiers you have submitted.
3.2.P.8	• Please submit documents / information of this section for stability studies of minimum 03 batches both at accelerated and long term stability conditions which must contains i. stability sheets with batch No., Batch size, Manufacturing date, expiry date, API Lot # used in batch manufacturing, date of initiation of testing. ii. Chromatograms along with raw data. iii. Calculation sheets which should have essential parameter such as weight in mg/gm of sample & standards, dilutions, formula of calculation as per USP Specifications etc. • Please submit DRAP clearance documents for API import.

	• Please submit COA of API LOT # used in manufacturing of stability batches.

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

Item No. 02: New Licenses / Sections

New Section

M/s Caraway Pharmaceuticals (DML # 000629) Rawat Central Licensing Board in its 287th meeting held on 24th June 2022 approved the grant of following additional section.

i. Liquid Syrup (General) – first floor

583.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Caraway Pharmaceuticals (DML # 000629)** **Plot # 12, Street #N-3, National Industrial Zone (RCCI), Rawat.**
	Name, address of Manufacturing site.	M/s Caraway Pharmaceuticals (DML # 000629) Plot # 12, Street #N-3, National Industrial Zone (RCCI), Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Validity: 21-02-2024
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21977 dated 06-09-2023
	Details of fee submitted	PKR 30,000/-: Dated 13-12-2023 Slip # 9497627580
	The proposed proprietary name / brand name	Disdine 0.5mg/ml Syrup
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of syrup contains: Desloratadine ……. 0.5 mg
	Pharmacotherapeutic Group of (API)	Antihistamines – H1 antagonist
	Pharmaceutical form of applied drug	Oral syrup
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	PET bottle 60 mL & 120 mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Neo-Antial(Desloratadine) 0.5 mg/mL Syrup (60 mL) Reg. No. 076064 by Sami Pharmaceuticals.
	Name and address of API manufacturer.	Name: Tagoor Laboratories Private Limited Address: Plot No.: 75, H.No.: 1 – 98/3, 1st and 2nd floor, Jubilee Enclave, Hitech City, Hyderabad, Telangana, India. GMP Validity: 14-05-2024
	Module-II (Quality Overall	Firm has submitted QOS as per WHO QOS-PD template. Firm has

	Summary)	summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Neo-Antial 0.5 mg/mL Syrup **Manufactured by:** M/s Sami Pharmaceuticals karachi **Testing Parameters:** Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: Metrochem API Private Limited, Unit - IV Name: Tagoor Laboratories Private Limited Address: Plot No.: 75, H.No.: 1 – 98/3, 1st and 2nd floor, Jubilee Enclave, Hitech City, Hyderabad, Telangana, India.		
API Lot No.	DLRD-00422		
Description of Pack (Container closure system)	PET BOTTLE		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	DIST001	DIST002	DIST003
Batch Size	1000 Bottles	1000 Bottles	1000 Bottles
Manufacturing Date	01/2023	01/2023	01/2023
Date of Initiation	13-01-2023	13-01-2023	13-01-2023
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 02 kg **Dated:** 22-12-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	• Please submit GMP certificate of API manufacturer issued by regulatory authority of the country of origin which should be valid till date.	Submitted
3.2.P.8	• In Section 3.2.P.7, amber colored glass bottle has been mentioned as the primary container of drug product while in stability summary sheets, PET bottle has been used as the primary container. Please clarify.	PET Bottle
	• Please submit in tabulated form the summary sheets of stability results of accelerated and long term stability conditions. The stability summary sheet must contain information regarding batch size, batch #, mfg. date, expiry date, date ofinitiation of studies, API LOT# used to manufacture stability batches, stability conditions, details of container closure system.etc	Submitted
	• Submit raw data along with chromatograms and calculation sheets.	Submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

New Section

M/s Wezen Pharmaceuticals (DML # 000882) Rawat.

Central Licensing Board in its 278th meeting held on 10th & 12th December 2020 approved the grant of four (04) additional sections of dosage forms.

ii. Tablet (General) Section.
iii. Capsule (General) Section.
iv. Sachet (General) Section.
v. Ointment / Cream / Gel (General)

584.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals. (DML # 000882)** **Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals. (DML # 000882) Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection report dated 04-12-2023 recommendation of Tablet Section.
	Evidence of approval of	New Section granted by CLB

	manufacturing facility	
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21977 dated 06-09-2023
	Details of fee submitted	PKR 75,000/-: Dated 05-09-2023 Slip # 263260505736
	The proposed proprietary name / brand name	TABLET PRUZEN 1 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Prucalopride Succinate 1.32 mg equivalent to Prucalopride ……. 1 mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl Peptidase-4 (Dpp-4) Inhibitor
	Pharmaceutical form of applied drug	Oral film coated tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved Motegrity® 1mg Tablet
	For generic drugs (me-too status)	Brand Name: Prucalp 1mg tablet Manufacturer: M/s Seraph (Reg. # 119163)
	Name and address of API manufacturer.	Name: Metrochem API Private Limited, Unit - IV Address: Plot # 34B, 40B & 60B J.N. Pharma City, Thanam Village, Parawada Mandal, Vishakhapatnam District, Andhra Pradesh, India. GMP Validity: 07-05-2027
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing

		process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Resolor 1 mg Tablet **Manufactured by:** Takeda Ireland **Testing Parameters:** Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Metrochem API Private Limited, Unit - IV Address: Plot # 34B, 40B & 60B J.N. Pharma City, Thanam Village, Parawada Mandal, Vishakhapatnam District, Andhra Pradesh, India.		
API Lot No.	PCS-P/22012		
Description of Pack (Container closure system)	ALU-ALU Blisters of 3 x 10's further packed in bleech card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T- 01	T- 02	T- 03
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	03-2023	03-2023	03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Material Loan Giver:** Horizon Healthcare Lahore **Quantity of Loan:** 20 grams **Quantity:** 01 kg **Dated:** 15-03-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	• Please submit GMP certificate of API manufacturer issued by regulatory authority of the country of origin which should be valid till date.	Submitted
3.2.P.1	• In the composition of film coating of tablets, applicant has used isopropyl alcohol (solvent) with Colorcoat FC4S (Hydroxypropyl Methylcellulose, Polydextrose Sugar, Polyvinyl Alcohol). While innovator product (Resolor) used Water as a solvent for film coating of the tablets including Hypromellose Lactose monohydrate Triacetin Titanium dioxide (E171) Macrogol. Please justify the difference in coating materials and use of IPA instead of water as solvent for coating?	The formulation was attached mistakenly and process may be confirmed from BMR attached at the end of dossier. Revised correct formulation attached along with manufacturing process.
3.2.P.8	• Please submit DRAP clearance documents for procurement of API by Horizon Healthcare Lahore. • Please submit COA of API with Lot # used in manufacturing of Stability batches. • Please submit complete data of stability studies due at the interval of 6th month for accelerated and real time conditions.	Submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

585.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals. (DML # 000882) Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals. (DML # 000882) Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection report dated 04-12-2023 recommendation of Tablet Section.
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21978 dated 06-09-2023
	Details of fee submitted	PKR 75,000/-: Dated 05-09-2023 Slip # 23967371647

	The proposed proprietary name / brand name	TABLET PRUZEN 2 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Prucalopride Succinate 2.64 mg equivalent to Prucalopride ……. 2 mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl Peptidase-4 (Dpp-4) Inhibitor
	Pharmaceutical form of applied drug	Oral film coated tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved Motegrity® 2mg Tablet
	For generic drugs (me-too status)	Brand Name: Prucalp 2mg tablet Manufacturer: M/s Seraph (Reg. # 119162)
	Name and address of API manufacturer.	Name: Metrochem API Private Limited, Unit - IV Address: Plot # 34B, 40B & 60B J.N. Pharma City, Thanam Village, Parawada Mandal, Vishakhapatnam District, Andhra Pradesh, India. GMP Validity:
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Resolor 2 mg Tablet **Manufactured by:** Takeda Ireland **Testing Parameters:** Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums

		showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Metrochem API Private Limited, Unit - IV Address: Plot # 34B, 40B & 60B J.N. Pharma City, Thanam Village, Parawada Mandal, Vishakhapatnam District, Andhra Pradesh, India.		
API Lot No.	PCS-P/22012		
Description of Pack (Container closure system)	ALU-ALU Blisters of 3 x 10's further packed in bleech card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T- 04	T- 05	T- 06
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	03-2022	03-2022	03-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Material Loan Giver:** Horizon Healthcare Lahore **Quantity of Loan:** 20 grams **Quantity:** 01 kg **Dated:** 15-03-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	• Please submit GMP certificate of API manufacturer issued by regulatory authority of the country of origin which should be valid till date.	Submitted

3.2.P.1	• In the composition of film coating of tablets, applicant has used isopropyl alcohol (solvent) with Colorcoat FC4S (Hydroxypropyl Methylcellulose, Polydextrose Sugar, Polyvinyl Alcohol). While innovator product (Resolor) used Water as a solvent for film coating of the tablets including Hypromellose Lactose monohydrate Triacetin Titanium dioxide (E171) Macrogol. Please justify the difference in coating materials and use of IPA instead of water as solvent for coating?	The formulation was attached mistakenly and process may be confirmed from BMR attached at the end of dossier. Revised correct formulation attached along with manufacturing process.
3.2.P.8	• Please submit DRAP clearance documents for procurement of API by Horizon Healthcare Lahore. • Please submit COA of API with Lot # used in manufacturing of Stability batches. • Please submit complete data of stability studies due at the interval of 6th month for accelerated and real time conditions.	Submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

586.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals. (DML # 000882) Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals. (DML # 000882) Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection report dated 04-12-2023 recommendation of Tablet Section.
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. ZGY-T8Q-5JSG dated 02-02-2024
	Details of fee submitted	PKR 30,000/-: Dated 31-01-2024 Slip # 3673113632
	The proposed proprietary name / brand name	**Eenox 20mg/375mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Naproxen (enteric coated core) …… 375 mg Esomeprazole as magnesium tri-hydrate (immediate release coat)…… 20 mg
	Pharmacotherapeutic Group of (API)	Anti-inflammatory And Anti-rheumatic Products, Non Steroids - Priopionic Acid Derivatives

	Pharmaceutical form of applied drug	Oral film coated tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	3 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved VIMOVO
	For generic drugs (me-too status)	Eznepo MR Tablet 375/20mg Reg# 117965
	Name and address of API manufacturer.	**Esomeprazole Magnesium Trihydrate** Name: Metrochem API Private Limited, Unit - IV Address: Plot No. 62/C/6, PIPELINE ROAD, PHASE-I, I.D.A, JEEDIMETLA, QUTHBULLAPUR (M), MEDCHAL (DIST), INDIA. GMP Validity: 26-09-2025 **Naproxen** Name: Divi's Laboratoires Limited Address: 1-72/23(P)/DIVIS/303, Divi Towers, Cyber Hills, Gachibowli, Hyderabad – 500 032, Telangana, INDIA. GMP Validity: 26-06-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Esomeprazole Magnesium Trihydrate** Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 60 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH **Naproxen** Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 60 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Tablet Glomov **Manufactured by:** Global Pharma **Testing Parameters:** Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Esomeprazole Magnesium Trihydrate** Name: Metrochem API Private Limited, Unit - IV Address: Plot No. 62/C/6, PIPELINE ROAD, PHASE-I, I.D.A, JEEDIMETLA, QUTHBULLAPUR (M), MEDCHAL (DIST), INDIA. GMP Validity: 26-09-2025 **Naproxen** Name: Divi's Laboratoires Limited Address: 1-72/23(P)/DIVIS/303, Divi Towers, Cyber Hills, Gachibowli, Hyderabad – 500 032, Telangana, INDIA. GMP Validity: 26-06-2024		
API Lot No.	**Esomeprazole Magnesium Tri-hydrate**	**Naproxen**	
	ESM/2210436	2-M-C-3541022	
Description of Pack (Container closure system)	ALU-ALU Blisters of 1 x 10's further packed in bleech card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T- 04	T- 05	T- 06
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	01-02-2023	01-02-2023	01-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Esomeprazole Magnesium Tri-Hydrate** **Material Loan Giver:** Winbrains Research Laboratories **Quantity of Loan:** 200 grams **Quantity:** 150 kg **Dated:** 31-10-2022 **Naproxen** **Material Loan Giver:** Wetherfolds Pharmaceuticals **Quantity of Loan:** 3.5 KG

		Quantity: 500 kg **Dated:** 20-10-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.P.3	• Please submit manufacturing process as per the steps of core tablet formulation, enteric coatings, drug layer coating and film coating as explained in your master formulation. Also highlight the critical process parameters and CQAs.	Submitted
3.2.P.5	• Please submit in-process tests for the drug layer coating.	Submitted
3.2.P.8	• Please fill in the stability sheets for the dissolution results for the last month interval (06th month)	Submitted
	• Please clarify that why name of analyst has not been mentioned at "Data acquired by" in sample information window of chromatograms.	All details were filled when the project was setup initially on system, as it was 6th month stability and not performed by same analyst, so the name was not mentioned. Next time we will work on it.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

587.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals. (DML # 000882) Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals. (DML # 000882) Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection report dated 04-12-2023 recommendation of Tablet Section.
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No AJH-J65-4T5L dated 02-02-2024
	Details of fee submitted	PKR 30,000/-: Dated 31-01-2024

		Slip # 71824443
	The proposed proprietary name / brand name	**Eenox 20mg/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Naproxen (enteric coated core) …… 500 mg Esomeprazole as magnesium tri-hydrate (immediate release coat)…… 20 mg
	Pharmacotherapeutic Group of (API)	Antiinflammatory And Antirheumatic Products, Non Steroids - Priopionic Acid Derivatives
	Pharmaceutical form of applied drug	Oral film coated tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	3 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved VIMOVO
	For generic drugs (me-too status)	Eznepo MR Tablet 500/20mg Reg# 117966 By Wnsfeild Pharmaceuticals
	Name and address of API manufacturer.	**Esomeprazole Magnesium Trihydrate** Name: Metrochem API Private Limited, Unit - IV Address: Plot No. 62/C/6, PIPELINE ROAD, PHASE-I, I.D.A, JEEDIMETLA, QUTHBULLAPUR (M), MEDCHAL (DIST), INDIA. GMP Validity: 26-09-2025 **Naproxen** Name: Divi's Laboratoires Limited Address: 1-72/23(P)/DIVIS/303, Divi Towers, Cyber Hills, Gachibowli, Hyderabad – 500 032, Telangana, INDIA. GMP Validity: 26-06-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Esomeprazole Magnesium Trihydrate** Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 60 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH **Naproxen** Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH

		Real time stability data for 60 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Tablet Glomov **Manufactured by:** Global Pharma **Testing Parameters:** Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**<u>Esomeprazole Magnesium Trihydrate</u>** Name: Metrochem API Private Limited, Unit - IV Address: Plot No. 62/C/6, PIPELINE ROAD, PHASE-I, I.D.A, JEEDIMETLA, QUTHBULLAPUR (M), MEDCHAL (DIST), INDIA. GMP Validity: 26-09-2025 **<u>Naproxen</u>** Name: Divi's Laboratoires Limited Address: 1-72/23(P)/DIVIS/303, Divi Towers, Cyber Hills, Gachibowli, Hyderabad – 500 032, Telangana, INDIA. GMP Validity: 26-06-2024		
API Lot No.	**Esomeprazole Magnesium Tri-hydrate**		**Naproxen**
	ESM/2210436		2-M-C-3541022
Description of Pack (Container closure system)	ALU-ALU Blisters of 1 x 10's further packed in bleech card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T- 01	T- 02	T- 03
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	01-02-2023	01-02-2023	01-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Esomeprazole Magnesium Tri-Hydrate** **Material Loan Giver:** Winbrains Research Laboratories **Quantity of Loan:** 200 grams **Quantity:** 150 kg **Dated:** 31-10-2022 **Naproxen** **Material Loan Giver:** Wetherfolds Pharmaceuticals **Quantity of Loan:** 3.5 KG **Quantity:** 500 kg **Dated:** 20-10-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.P.3	• Please submit manufacturing process as per the steps of core tablet formulation, enteric coatings, drug layer coating and film coating as explained in your master formulation. Also highlight the critical process parameters and CQAs.	Submitted
3.2.P.5	• Please submit in-process tests for the drug layer coating.	Submitted
3.2.P.8	• Please fill in the stability sheets for the dissolution results for the last month interval (06th month)	Submitted
	• Please clarify that why name of analyst has not been mentioned at "Data acquired by" in sample information window of chromatograms.	All details were filled when the project was setup initially on system, as it was 6th month stability and not performed by same analyst, so the name was not mentioned. Next time we will work on it.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

588.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals. (DML # 000882)** **Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals. (DML # 000882) Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection report dated 04-12-2023 recommendation of Tablet Section.

	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 1A5-62S-RNQE dated 03-02-2024
	Details of fee submitted	PKR 30,000/-: Dated 31-01-2024 Slip # 99389060
	The proposed proprietary name / brand name	BILTEX 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each unoated tablet contains: Bilastine …… 20 mg
	Pharmacotherapeutic Group of (API)	Antihistamines for systemic use,
	Pharmaceutical form of applied drug	Oral tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Bilaxten 20 mg Tablet by AGP
	Name and address of API manufacturer.	Name: Metrochem API Private Limited, Unit - IV Address: Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, 531021, India (IND). GMP Validity: 07-05-2027
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 12 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description,

		composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Tablet Bilaxten 20mg **Manufactured by:** A.Menarini, Italy **Testing Parameters:** Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Metrochem API Private Limited, Unit - IV Address: Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, 531021, India (IND).		
API Lot No.	CUB-P/22002		
Description of Pack (Container closure system)	ALU-ALU Blisters of 1 x 10's further packed in bleech card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T- 01	T- 02	T- 03
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	08-2023	08-2023	08-2023
Date of Initiation	26-08-2023	26-08-2023	26-08-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Material Loan Giver:** Wetherfold Pharmaceuticals **Quantity of Loan:** 500 grams
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.P.3	• Please submit process validation of manufacturing with respect to the nature of the product.	Submitted
	• Please submit critical process parameters to determine critical quality attributes.	Submitted
	• Please clarify the manufacturing method of the tablet either direct compression or by wet granulation?	By direct compression
	• Please submit precautionary measures taken to identify polymorphic form of API and its undesired polymorphic conversion of anhydrous solid form of API to a hydrate form during the tablet manufacturing.	Submitted
3.2.P.5	• Please submit stability data of the three batches both at accelerated and long term studes for the last interval (06th month).	Submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

589.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals. (DML # 000882) Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals. (DML # 000882) Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection report dated 04-12-2023 recommendation of Tablet Section.
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No SYX-QZM-ZJJ8 dated 03-02-2024
	Details of fee submitted	PKR 30,000/-: Dated 31-01-2024 Slip # 8448740050
	The proposed proprietary name / brand name	BILTEX 10mg Orodispersible Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Orodispersible tablet contains: Bilastine …… 10 mg
	Pharmacotherapeutic Group of (API)	Antihistamines for systemic use,
	Pharmaceutical form of applied drug	Oral tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Name: Metrochem API Private Limited, Unit - IV Address: Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, 531021, India (IND). GMP Validity: 07-05-2027
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 12 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Orodispersible Tablet Bilaxten 10mg **Manufactured by:** A.Menarini, Italy **Testing Parameters:** Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Name: Metrochem API Private Limited, Unit - IV Address: Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, 531021, India (IND).
API Lot No.	CUB-P/22002
Description of Pack (Container closure system)	ALU-ALU Blisters of 1 x 10's further packed in bleech card unit carton along with leaflet.

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T- 04	T- 05	T- 06
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	08-2023	08-2023	08-2023
Date of Initiation	26-08-2023	26-08-2023	26-08-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Material Loan Giver:** Wetherfold Pharmaceuticals **Quantity of Loan:** 500 grams
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.1	• As Bilatine Orodispersible Tablet is not yet marketed in Pakistan therefore please submit the differential fee of PKR 45000/- for the status of your application as New Drug Application.	Submitted Slip # 191325873 Dated: 04-03-24
3.2.P.1 To 3.2.P.3	• The Module III submitted belongs to drug product Bilastine 20 mg Film coated tablet while the product applied is Orodispersible tablet 10 mg. please submit Module III for Orodispersible 10 mg tablet.	Submitted
3.2.P.8	• Please submit stability data of three batches both for accelerated as well as long term conditions for the last interval (06th month).	Submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

New Section

Central Licensing Board in its 285th meeting held on 17th & 18th March 2022 approved the grant to additional section 'Dry Powder Sachet Section (General)' in the premises of M/s Titlis Pharma (Private) Limited. (DML # 000799) 528-A Sundar Industrial Estate, Raiwind Road Lahore.

590.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Titlis Pharma (Private) Limited. (DML # 000799) 528-A Sundar Industrial Estate, Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Titlis Pharma (Private) Limited. (DML # 000799) 528-A Sundar Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP validity: 11-12-2024
	Evidence of approval of manufacturing facility	New Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. TTZ-L55-B9A8 dated 04-12-2023
	Details of fee submitted	PKR 30,000/-: Dated 27-11-2023 Slip # 11805203530
	The proposed proprietary name / brand name	ORS Sachet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Sodium Chloride…….…… 2.60 gm Trisodium citrate dihydrate….2.90 gm Potassium Chloride…… 1.50 gm Glucose Anhydrous……13.50 gm
	Pharmaco-therapeutic Group of (API)	Electrolytes and Carbohydrates
	Pharmaceutical form of applied drug	Oral Rehydration Salts (ORS)
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	20’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Antidiarrheal remedy of reduced osmolarity ORS solution recommended by UNICEF.
	For generic drugs (me-too status)	Werisol (O.R.S) by Werrick Pharmaceuticals
	Name and address of API manufacturer.	**<u>Sodium Chloride, Potassium Chloride, Trisodium citrate dihydrate</u>** Name: Rasino herbs (Pvt.) Ltd. Address: N-2, MIDC, Chemical Zone Kupwad, Sangli 416436, Maharastra – India. GMP validity: 20-02-2024 **<u>Glucose Anhydrous</u>** Name: Weifang Shengtai Medicine Co., Ltd Address: The east of Changda Road, Development District Changle County, China. GMP validity: 14-10-2023
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of

		manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Sodium Chloride** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH **Glucose Anhydrous** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH **Potassium Chloride** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH **Trisodium Citrate di-hydrate** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** ORAES (ORS) Sachet **Manufactured by:** Axis Pharmaceuticals. **Testing Parameters:** BP Specification
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**<u>Sodium Chloride, Potassium Chloride, Trisodium citrate dihydrate</u>** Name: Rasino herbs (Pvt.) Ltd. Address: N-2, MIDC, Chemical Zone Kupwad, Sangli 416436, Maharastra – India. GMP validity: 20-02-2024 **<u>Glucose Anhydrous</u>** Name: Weifang Shengtai Medicine Co., Ltd Address: The east of Changda Road, Development District Changle County, China. GMP validity: 16-12-2024
API Lot No.	NAPB22119, KP22107, SCP22003, 20230225-1

Description of Pack (Container closure system)	White colored free flowing granules with orange flavor filled in aluminum foil sachet packed in 1 x 20"s Cardboard carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	OR-01	OR-02	OR-03
Batch Size	42 Sachet	42 Sachet	42 Sachet
Manufacturing Date	June - 2023	June - 2023	June - 2023
Date of Initiation	26/06/2023	26/06/2023	26/06/2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Glucose Anhydrous** Clearance date: 30-03-2023 Quantity: 25 kg **Sodium Chloride** Clearance date: 20-03-2023 Quantity: 570 gm **Potassium Chloride** Clearance date: 20-03-2023 Quantity: 270 gm **Trisodium Citrate** Clearance date: 20-03-2023 Quantity: 420 gm
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	• Please submit GMP certificate API manufacturer "Weifang Shengtai Medicine Co. Ltd" issued by regulatory authority of country of origin which should be valid till date.	Submitted
3.2.P.8	• Please submit the stability data of the last interval (6th month)	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

New Section Central Licensing Board in its 284th meeting held on 16th December 2021, approved the grant of additional section **'Eye/Ear/Nose Drop Section'** to M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21-km ferozpur road Lahore.		
591.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577)** **21km feorzpur road Lahore.**
	Name, address of Manufacturing site.	M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km feorzpur road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate of the firm issued on the basis of inspection report dated 29th October 2024.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 284th meeting held on 16th December 2021, approved the grant of two (02) additional sections including Eye/Ear/Nose Drop Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 33J-J44-PXR9 dated 10-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 05-09-2023 Slip # 199883913
	The proposed proprietary name / brand name	Nefen Ophthalmic Suspension 0.1%W/V
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Nepafenac ……. 1 mg
	Pharmaco-therapeutic Group of (API)	Nonsteroidal anti-inflammatory drugs (NSAIDs).
	Pharmaceutical form of applied drug	Ophthalmic suspension
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	Sterile Eye Drops packed in LDPE bottles
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nevanac® by Novartis MHRA approved formulation
	For generic drugs (me-too status)	Nevanac by AGP (Reg. # 47563)
	Name and address of API manufacturer.	Name: Shaoxing Zhongchang Scientific Co, Ltd Address: Shangyu Chemical Zone, Zhejiang, China. GMP validity : 28-09-2023
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Nepanac Ophthalmic suspension **Manufactured by:** Remington Pharma. **Testing Parameters:** Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Shaoxing Zhongchang Scientific Co, Ltd Address: Shangyu Chemical Zone, Zhejiang, China.		
API Lot No.	20220501		
Description of Pack (Container closure system)	Light yellow color viscous suspension filled in sterilized Dropper Bottle equipped with sterilized Nozzle and cap, further packed in unit carton along with Leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	192 bottles	192 bottles	192 bottles
Manufacturing Date	09 -2022	09 -2022	09 -2022
Date of Initiation	29-09-2022	29-09-2022	29-09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Clearance date: 08-06-2022 Quantity: 100 grams
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.P.2	Please justify that why manufacturer has chosen sterilising the nepafenac mixture in autoclave while it is a heat sensitive active ingredient?	It was attached mistakenly. Firm has submitted revised method of manufacturing according to the nature of product.
	Please justify that why the "milling" of Nepafenac to ensure uniform particle size in the suspension formulation, has not been considered a major step in controlling quality of product. *(The particle size distribution data during the stability evaluation indicate that there are slight changes in the particle size distribution during long term storage).*	We are using API having particle size less than 10 microns in our formulation. COA is attached for reference.
3.2.P.8	Please submit COA of API Lot used in pharmaceutical development & manufacturing of stability batches issued by both API supplier as well as drug product manufacturer.	Submitted
	Please submit DRAP Clearance documents for procurement of API.	Submitted
	Please justify that why viscosity test has not been involved in testing parameters of your drug product while it is a major test in innovator specification because a decrease in product viscosity was observed with time during storage.	Firm has submitted revised COA of finished product including all anaylytical test as per innovator specifications.
	Please submit the stability data sheets containing all tests as mentioned in Innovator specifications for drug product i.e. appearance of suspension, identity (TLC, HPLC), assay (HPLC), identity and assay of benzalkonium chloride (HPLC), identity and assay of sodium edetate (HPLC), pH (Ph.Eur.), osmolality (Ph.Eur.), redispersibility, viscosity (Ph.Eur.), particle size (light diffraction), fill volume and sterility (Ph.Eur.).	Submitted
	Please submit water loss studies protocol and calculation sheets for ratio of water loss at low humidity testing conditions and alternative testing conditions along with printed weights taken from analytical balance.	Submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

592.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.**
	Name, address of Manufacturing site.	M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate of the firm issued on the basis of inspection report dated 29th October 2024.
	Evidence of approval of manufacturing facility	Not provided
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. N97-E6T-3NQZ dated 15-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 05-09-2023 Slip # 57497970
	The proposed proprietary name / brand name	Nefen Ophthalmic Suspension 0.3% w/v
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Nepafenac ……. 3 mg
	Pharmaco-therapeutic Group of (API)	Nonsteroidal anti-inflammatory drugs (NSAIDs).
	Pharmaceutical form of applied drug	Ophthalmic suspension
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	Sterile Eye Drops packed in LDPE bottles
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nevanac® by Novartis MHRA approved formulation
	For generic drugs (me-too status)	Ilevro Eye drops suspension *(Reg # 095874)* Novartis Pharma (Pakistan) Limited
	Name and address of API manufacturer.	Name: Shaoxing Zhongchang Scientific Co, Ltd Address: Shangyu Chemical Zone, Zhejiang, China. GMP validity : 28-09-2023
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months

		Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Nepanac Ophthalmic suspension **Manufactured by:** Remington Pharma. **Testing Parameters:** Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Shaoxing Zhongchang Scientific Co, Ltd Address: Shangyu Chemical Zone, Zhejiang, China.		
API Lot No.	20220501		
Description of Pack (Container closure system)	Light yellow color viscous suspension filled in sterilized Dropper Bottle equipped with sterilized Nozzle and cap, further packed in unit carton along with Leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	1 Liter	1 Liter	1 Liter
Manufacturing Date	10 -2022	10 -2022	10 -2022
Date of Initiation	26-10-2022	26-10-2022	26-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Clearance date: 08-06-2022 Quantity: 100 grams
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm

3.2.P.2	Please justify that why manufacturer has chosen sterilising the nepafenac mixture in autoclave while it is a heat sensitive active ingredient?	It was attached mistakenly. Firm has submitted revised method of manufacturing according to the nature of product.
	Please justify that why the "milling" of Nepafenac to ensure uniform particle size in the suspension formulation, has not been considered a major step in controlling quality of product. *(The particle size distribution data during the stability evaluation indicate that there are slight changes in the particle size distribution during long term storage).*	We are using API having particle size less than 10 microns in our formulation. COA is attached for reference.
3.2.P.8	Please submit COA of API Lot used in pharmaceutical development & manufacturing of stability batches issued by both API supplier as well as drug product manufacturer.	Submitted
	Please submit DRAP Clearance documents for procurement of API.	Submitted
	Please justify that why viscosity test has not been involved in testing parameters of your drug product while it is a major test in innovator specification because a decrease in product viscosity was observed with time during storage.	Firm has submitted revised COA of finished product including all analytical test as per innovator specifications.
	Please submit the stability data sheets containing all tests as mentioned in Innovator specifications for drug product i.e. appearance of suspension, identity (TLC, HPLC), assay (HPLC), identity and assay of benzalkonium chloride (HPLC), identity and assay of sodium edetate (HPLC), pH (Ph.Eur.), osmolality (Ph.Eur.), redispersibility, viscosity (Ph.Eur.), particle size (light diffraction), fill volume and sterility (Ph.Eur.).	Submitted
	Please submit water loss studies protocol and calculation sheets for ratio of water loss at low humidity testing conditions and alternative testing conditions along with printed weights taken from analytical balance.	Submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

593.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.**
	Name, address of Manufacturing site.	M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate of the firm issued on the basis of inspection report dated 29th October 2024.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 284th meeting held on 16th December 2021, approved the grant of two (02) additional sections including Eye/Ear/Nose Drop Section.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3HZ-ZLZ-SZVE dated 15-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 05-09-2023 Slip # 739675309669
	The proposed proprietary name / brand name	M.Cip Ophthalmic Solution 0.3% w/v
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: 3.5mg of Ciprofloxacin Hydrochloride equivalent to Ciprofloxacin base …….3mg
	Pharmaco-therapeutic Group of (API)	Fluoroquinolone.
	Pharmaceutical form of applied drug	Ophthalmic solution
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	Sterile Eye Drops packed in LDPE bottles
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation Ciloxan ®
	For generic drugs (me-too status)	Rocip Ophthalmic Solution *(Reg #* 015693*)* Remington Pharmaceutical (Pvt.) Ltd.
	Name and address of API manufacturer.	Name: M/s Citi Pharma (Pvt.) Ltd Address: 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur - 55050 Punjab, Pakistan GMP validity : 02-03-2026
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials,

		container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Rocip Ophthalmic Solution 0.3% **Manufactured by:** Remington Pharmaceutical(Pvt.) Ltd. **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: M/s Citi Pharma (Pvt.) Ltd Address: 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan		
API Lot No.	CPH2210114		
Description of Pack (Container closure system)	Clear, transparent Solution filled in sterilized Dropper Bottle equipped with sterilized Nozzle and cap, further packed in unit carton along with Leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-006	T-007	T-008
Batch Size	1 Liter	1 Liter	1 Liter
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	09-01-2023	09-01-2023	09-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Clearance date: Locally procured Quantity:
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.3.4	Please submit section approval letter for ophthalmic section issued after approval in meeting of Central Licensing Board.	Submitted
3.2.P.8	Please submit water loss studies protocol and calculation sheets for ratio of water loss at low humidity testing conditions and alternative testing conditions along with printed weights taken from analytical balance.	Submitted

Decision: Approved.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
594.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.**
	Name, address of Manufacturing site.	M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate of the firm issued on the basis of inspection report dated 29th October 2024.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 284th meeting approved the grant of additional sections including the manufacturing facility of Eye/Ear/Nose Drops Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 85E-7UN-31V9 dated 20-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 31-08-2023 Slip # 739675309669
	The proposed proprietary name / brand name	Opadin Ophthalmic Solution 0.1 % w/v
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Olopatadine HCl equivalent to Olopatadine ……. 1 mg
	Pharmaco-therapeutic Group of (API)	Ophthalmological; decongestant and anti-allergic
	Pharmaceutical form of applied drug	Ophthalmic solution
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	Sterile Eye Drops packed in LDPE bottles
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Zolopat Ophthalmic Solution 0.1%w/v (Reg # 065991) Remington Pharmaceutical (Pvt.) Ltd.
	Name and address of API manufacturer.	Name: Shaoxing Zhongchang Scientific Co, Ltd Address: Shangyu Chemical Zone, Zhejiang, China. GMP validity : 19-12-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Zolopat Ophthalmic Solution 0.1%w/v **Manufactured by:** Remington Pharmaceutical(Pvt.) Ltd. **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Shaoxing Zhongchang Scientific Co, Ltd Address: Shangyu Chemical Zone, Zhejiang, China.		
API Lot No.	20211201		
Description of Pack (Container closure system)	Clear colorless solution, filled in sterilized Dropper Bottle equipped with sterilized Nozzle and cap, further packed in unit carton along with Leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	1 Liter	1 Liter	1 Liter
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	27-11-2022	27-11-2022	27-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Clearance date: 200 grams Quantity: 08-06-2022

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

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.3.4	Please submit section approval letter for ophthalmic section issued after approval in meeting of Central Licensing Board.	Submitted
1.5.5	As per your claim of olopatadine as NSAID, please provide reference.	Correction done. Antihistamine
1.6.5	Please provide GMP certificate of API manufacturer issued by regulatory authority of country of origin and should be valid till date.	Submitted
3.2.P.8	Please submit water loss studies protocol and calculation sheets for ratio of water loss at low humidity testing conditions and alternative testing conditions along with printed weights taken from analytical balance.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

595.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.**
	Name, address of Manufacturing site.	M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate of the firm issued on the basis of inspection report dated 29th October 2024.
	Evidence of approval of manufacturing facility	Not provided
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. M34-TG3-LAGL dated 21-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 31-08-2023 Slip # 64317993
	The proposed proprietary name / brand name	Opadin Ophthalmic Solution 0.2 % w/v
	Strength / concentration of drug of Active Pharmaceutical ingredient	Each ml contains: Olopatadine HCl equivalent to

	(API) per unit	Olopatadine …… 2 mg
	Pharmaco-therapeutic Group of (API)	Ophthalmological; decongestant and anti-allergic
	Pharmaceutical form of applied drug	Ophthalmic solution
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	Sterile Eye Drops packed in LDPE bottles
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation Pataday®
	For generic drugs (me-too status)	Zolopat Forte Ophthalmic Solution 0.2% (Reg # 069154) Remington Pharmaceutical (Pvt.) Ltd.
	Name and address of API manufacturer.	Name: Shaoxing Zhongchang Scientific Co, Ltd Address: Shangyu Chemical Zone, Zhejiang, China. GMP validity : 28-09-2023
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Zolopat Ophthalmic Solution 0.2%w/v **Manufactured by:** Remington Pharmaceutical(Pvt.) Ltd. **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Name: Shaoxing Zhongchang Scientific Co, Ltd Address: Shangyu Chemical Zone, Zhejiang, China.
API Lot No.	20211201
Description of Pack (Container closure system)	Clear colorless solution, filled in sterilized Dropper Bottle equipped with sterilized Nozzle and cap, further packed in unit carton along with Leaflet.

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-003	T-004	T-003
Batch Size	1 Liter	1 Liter	1 Liter
Manufacturing Date	01-2023	11-2022	11-2022
Date of Initiation	11-01-2023	11-01-2023	11-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Clearance date: 200 grams Quantity: 08-06-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.3.4	Please submit section approval letter for ophthalmic section issued after approval in meeting of Central Licensing Board.	Submitted
1.5.5	As per your claim of olopatadine as NSAID, please provide reference.	Correction done. Antihistamine
1.6.5	Please provide GMP certificate of API manufacturer issued by regulatory authority of country of origin and should be valid till date.	Submitted
3.2.P.8	Please submit water loss studies protocol and calculation sheets for ratio of water loss at low humidity testing conditions and alternative testing conditions along with printed weights taken from analytical balance.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

596.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.**
	Name, address of Manufacturing site.	M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate of the firm issued on the basis of inspection report dated 29th October 2024.
	Evidence of approval of manufacturing facility	New Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7168 dated 13-03-2023
	Details of fee submitted	PKR 30,000/-: Dated 16-02-2023 Slip # 203942757
	The proposed proprietary name / brand name	Lefexy Ophthalmic Solution 0.5 % w/v
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Levofloxacin hemihydrate equivalent to Levofloxacin ……. 5 mg
	Pharmaco-therapeutic Group of (API)	Fluoroquinolones
	Pharmaceutical form of applied drug	Ophthalmic solution
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	Sterile Eye Drops packed in LDPE bottles
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation Quixin®
	For generic drugs (me-too status)	Opticin 0.5% w/v eye drops by Ethical Laboratories
	Name and address of API manufacturer.	Name: Zheijiang East-Asia Pharmaceutical Co. Ltd. Address: Coastal Industrial City, Puhagang Town, Sanmen county, Zhejiang, China. GMP validity : 24-05-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Accelerated stability data for 06 months

	(Conditions & duration of Stability studies)	Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Zolopat Ophthalmic Solution 0.2%w/v **Manufactured by:** Remington Pharmaceutical(Pvt.) Ltd. **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Shaoxing Zhongchang Scientific Co, Ltd Address: Shangyu Chemical Zone, Zhejiang, China.		
API Lot No.	20211201		
Description of Pack (Container closure system)	Clear colorless solution, filled in sterilized Dropper Bottle equipped with sterilized Nozzle and cap, further packed in unit carton along with Leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-003	T-004	T-003
Batch Size	1 Liter	1 Liter	1 Liter
Manufacturing Date	01-2023	11-2022	11-2022
Date of Initiation	11-01-2023	11-01-2023	11-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Clearance date: 200 grams Quantity: 08-06-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	• Please provide GMP certificate of API manufacturer issued by regulatory authority of country of origin and should be valid till date.	Submitted
3.2.P.8	• Please submit water loss studies protocol and calculation sheets for ratio of water loss at low humidity testing conditions and alternative testing conditions along with printed weights taken from analytical balance.	Submitted
	• Please submit complete stability data for the last interval (06th month) for both accelerated and real time conditions.	Submitted
	• Please submit summary of stability studies at each interval (0,3,6 month) at accelerated and real time conditions separately, as per following format:	Submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

597.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.**
	Name, address of Manufacturing site.	M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate of the firm issued on the basis of inspection report dated 29th October 2024.
	Evidence of approval of manufacturing facility	New Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7QR-N8X-DX3Z dated 30-01-2024
	Details of fee submitted	PKR 30,000/-: Dated 05-09-2023 Slip # 4240641538
	The proposed proprietary name / brand name	MXN eye drops 0.5 % w/v
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Moxifloxacin (as HCl) ……. 5 mg
	Pharmaco-therapeutic Group of (API)	Fluoroquinolones
	Pharmaceutical form of applied drug	Ophthalmic solution
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	Sterile Eye Drops packed in LDPE bottles

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Moxian Eye drops by Barrett
	Name and address of API manufacturer.	Shankus Pharmaceuticals, Plot No 9,10,11 Milan Industrial Estate, Santej, Ta: Kalol, Dist: Gandhinagar - 382721, Gujarat, India GMP validity: 04-09-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 48 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Moxigan 0.5% w/v Eye Drops **Manufactured by:** Remington Pakistan **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Shankus Pharmaceuticals, Plot No 9,10,11 Milan Industrial Estate, Santej, Ta: Kalol, Dist: Gandhinagar - 382721, Gujarat, India
API Lot No.	MOX20130
Description of Pack (Container closure system)	Clear colorless solution, filled in sterilized Dropper Bottle equipped with sterilized Nozzle and cap, further packed in unit carton along with Leaflet.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)

Batch No.	T-006	T-007	T-008
Batch Size	192 bottles	192 bottles	192 bottles
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	09-01-2023	09-01-2023	09-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Clearance date: 200 grams Quantity: 08-06-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.P.8	• Please submit water loss studies protocol and calculation sheets for ratio of water loss at low humidity testing conditions and alternative testing conditions along with printed weights taken from analytical balance.	Submitted
	• Please submit API procurement documents approved by DRAP.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

598.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.**
	Name, address of Manufacturing site.	M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate of the firm issued on the basis of inspection report dated 29th October 2024.
	Evidence of approval of manufacturing facility	New Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. GZG-TQS-YDQZ dated 11-03-2024
	Details of fee submitted	PKR 30,000/-: Dated 05-09-2023 Slip # 3484311638
	The proposed proprietary name / brand name	**OLMA eye drops 0.25 % w/v**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Timolol (as Maleate) ……. 2.5 mg
	Pharmaco-therapeutic Group of (API)	Nonselective beta-adrenergic antagonist
	Pharmaceutical form of applied drug	Ophthalmic solution
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	Sterile Eye Drops packed in LDPE bottles
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA formulation approved formulation (Timoptic®)
	For generic drugs (me-too status)	Blotim Eye drops by Remingtion Pakistan
	Name and address of API manufacturer.	FLAX LABORATORIES PRIVATE LIMITED B-29/1, MIDC Mahad, Birvadi village, Dist: Raigad, Maharashtra, India-402301 GMP validity: 13-03-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 48 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Blotim Ophthalmic Solution 0.25% w/v **Manufactured by:** Remington Pakistan **Testing Parameters:** USP Specifications

	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	FLAX LABORATORIES PRIVATE LIMITED B-29/1, MIDC Mahad, Birvadi village, Dist: Raigad, Maharashtra, India-402301		
API Lot No.	TIM/22/001		
Description of Pack (Container closure system)	Clear colorless solution, filled in sterilized Dropper Bottle equipped with sterilized Nozzle and cap, further packed in unit carton along with Leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-003	T-004	T-005
Batch Size	192 bottles	192 bottles	192 bottles
Manufacturing Date	02-2023	01-2023	01-2023
Date of Initiation	28-02-2023	09-01-2023	09-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 1 kg **Dated:** 12-05-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.P.8	• Please submit water loss studies protocol and calculation sheets for ratio of water loss at low humidity testing conditions and alternative testing conditions along with printed weights taken from analytical balance.	Submitted
	• Please submit API procurement documents approved by DRAP.	Submitted
	• Please submit calculation for assay of drug product as per calculation formula provided in official monograph.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

599.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.**
	Name, address of Manufacturing site.	M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate of the firm issued on the basis of inspection report dated 29th October 2024.
	Evidence of approval of manufacturing facility	New Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. VV9-8JP-J5JV dated 30-01-2024
	Details of fee submitted	PKR 30,000/-: Dated 05-09-2023 Slip # 4543844381
	The proposed proprietary name / brand name	OLMA eye drops 0.5 % w/v
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Timolol (as Maleate) ……. 5 mg
	Pharmaco-therapeutic Group of (API)	Nonselective beta-adrenergic antagonist
	Pharmaceutical form of applied drug	Ophthalmic solution
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	Sterile Eye Drops packed in LDPE bottles
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA formulation approved formulation (Timoptic®)
	For generic drugs (me-too status)	Blotim Eye drops by Remingtion Pakistan
	Name and address of API manufacturer.	FLAX LABORATORIES PRIVATE LIMITED B-29/1, MIDC Mahad, Birvadi village, Dist: Raigad, Maharashtra, India-402301 GMP validity: 13-03-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 48 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Blotim Ophthalmic Solution 0.5% w/v **Manufactured by:** Remington Pakistan **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	FLAX LABORATORIES PRIVATE LIMITED B-29/1, MIDC Mahad, Birvadi village, Dist: Raigad, Maharashtra, India-402301		
API Lot No.	TIM/22/001		
Description of Pack (Container closure system)	Clear colorless solution, filled in sterilized Dropper Bottle equipped with sterilized Nozzle and cap, further packed in unit carton along with Leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	192 bottles	192 bottles	192 bottles
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	12-01-2023	12-01-2023	12-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 1 kg **Dated:** 12-05-2022

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

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.P.8	• Please submit water loss studies protocol and calculation sheets for ratio of water loss at low humidity testing conditions and alternative testing conditions along with printed weights taken from analytical balance.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

600.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.**
	Name, address of Manufacturing site.	M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate of the firm issued on the basis of inspection report dated 29th October 2024.
	Evidence of approval of manufacturing facility	New Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. J7L-Z8J-VHYH dated 22-03-2024
	Details of fee submitted	PKR 30,000/-: Dated 30-05-2023 Slip # 428326618
	The proposed proprietary name / brand name	KENVID eye drops 0.3 % w/v
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ofloxacin ……. 3 mg
	Pharmaco-therapeutic Group of (API)	Ophthalmologicals, anti-infectives, fluoroquinolones ATC code: S01AE01
	Pharmaceutical form of applied drug	Ophthalmic solution
	Reference to Finished product specifications	USP Specification

	Proposed Pack size	Sterile Eye Drops packed in LDPE bottles
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Ciof Eye drops by Remingtion Pakistan
	Name and address of API manufacturer.	Name: AARTI DRUGS LTD. Plot No. E – 120/119/105/106/104, M.I.D.C., Tarapur, Boisar, Tal. – Palghar, Dist.: Thane - 401 506. Maharashtra, INDIA GMP validity: 18-05-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Ciof Ophthalmic Solution 0.3% w/v **Manufactured by:** Remington Pakistan **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: AARTI DRUGS LTD. Plot No. E – 120/119/105/106/104, M.I.D.C., Tarapur, Boisar, Tal. – Palghar, Dist.: Thane - 401 506. Maharashtra, INDIA
API Lot No.	OPC/12090662
Description of Pack (Container closure system)	Clear colorless solution, filled in sterilized Dropper Bottle equipped with sterilized Nozzle and cap, further packed in unit carton along with Leaflet.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	192 bottles	192 bottles	192 bottles
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	02-09-2022	02-09-2022	02-09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 50 kg **Dated:** 12-03-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.P.8	• Please submit water loss studies protocol and calculation sheets for ratio of water loss at low humidity testing conditions and alternative testing conditions along with printed weights taken from analytical balance.	Submitted
	• Please submit API procurement documents approved by DRAP.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

601.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.**
	Name, address of Manufacturing site.	M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate of the firm issued on the basis of inspection report dated 29th October 2024.
	Evidence of approval of manufacturing facility	New Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical	☐ Domestic sale

	product	☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. MHU-UDX-QXBZ dated 14-03-2024
	Details of fee submitted	PKR 30,000/-: Dated 30-05-2023 Slip # 428326618
	The proposed proprietary name / brand name	S-dex Ophthalmic Suspension 0.1%W/V
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Dexamethasone ……. 1 mg
	Pharmaco-therapeutic Group of (API)	Ophthalmologicals, anti-inflammatory agents, Corticosteroids, plain, ATC code: S01B A01
	Pharmaceutical form of applied drug	Ophthalmic solution
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	Sterile Eye Drops packed in LDPE bottles
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation (Maxidex)
	For generic drugs (me-too status)	Maxidex Ophthalmic Solution 0.1% by Novartis
	Name and address of API manufacturer.	Zhejiang Xianju Pharmaceutical Co, Ltd 15 Vest Fengxi Road, Modern industrial Park, Xianju Zhejiang, China GMP validity: 08-04-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: °C ± 25°C / 60% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Maxidex ophthalmic suspension **Manufactured by:** Novartis **Testing Parameters:** USP Specifications

	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Xianju Pharmaceutical Co, Ltd 15 Vest Fengxi Road, Modern industrial Park, Xianju Zhejiang, China		
API Lot No.	P101-220203		
Description of Pack (Container closure system)	Clear colorless solution, filled in sterilized Dropper Bottle equipped with sterilized Nozzle and cap, further packed in unit carton along with Leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	294 bottles	294 bottles	294 bottles
Manufacturing Date	08-2023	08-2023	08-2023
Date of Initiation	30-08-2023	30-08-2023	30-08-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 500 grams **Dated:** 30-05-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.S.7	• Please submit stability data of API according to Zone IV-A requirement.	Submitted
3.2.P.8	• Please submit water loss studies protocol and calculation sheets for ratio of water loss at low humidity testing conditions and alternative testing conditions along with printed weights taken from analytical balance.	Submitted
	• Please submit API procurement documents approved by DRAP.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

New License: M/s JHK Pharma (Private) Ltd. (DML # 000946), Nowshera.

Central Licensing Board in its 285th meeting held on 17th & 18th March 2022 approved the grant DML # 000946 for following additional two (02) sections of dosage forms.

i. Ampoule SVP (General)

ii. Liquid Injectable Vials SVP (General) *in place of Intravenous infusion-LVP (General / Antibiotics)*

602.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Private)Ltd (DML # 000946) Khushal Khan Khattak Mazar Road, Akora Khattak, District Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Private)Ltd (DML # 000946) Khushal Khan Khattak Mazar Road, Akora Khattak, District Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New Section granted by CLB
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22821 dated 18-09-2023
	Details of fee submitted	PKR 75,000/-: Dated 25-10-2022 Slip # 4911267366
	The proposed proprietary name / brand name	J-Metro Injection 100 ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100 ml vial contains: Metronidazole ……. 500 mg
	Pharmacotherapeutic Group of (API)	Imidazole Derivatives
	Pharmaceutical form of applied drug	Sterile Solution for injection
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	LDPE bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Brand Name: Flazol Manufacturer: M/s Bosch
	Name and address of API manufacturer.	Name: AARTI DRUGS LTD. Address: Plot # 2902 – 2904, 2601 to 2605, 2509, G.I.D.C, Sarigam, Valsad, Guajarat, India. GMP Validity: 11-02-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Flagyl Infusion **Manufactured by:** Sanofi **Testing Parameters:** BP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: AARTI DRUGS LTD. Address: Plot # 2902 – 2904, 2601 to 2605, 2509, G.I.D.C, Sarigam, Valsad, Guajarat, India. GMP Validity:		
API Lot No.	WTZ/1040703		
Description of Pack (Container closure system)	LDPE Bottles		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T- 001	T- 02	T- 03
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	20-01-2023	20-01-2023	20-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Material Loan Giver:** Medicraft Pharmaceuticals, Hayatabad **Quantity:** 1000 kg **Invoice:** EXP/225/21-22 **Dated:** 02-06-2021 **Quantity of Loan:** 05kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	• Please submit GMP certificate of API manufacturer issued by regulatory authority of the country of origin which should be valid till date.	Submitted
3.2.S.7	• Please submit stability data of active ingredient climatic condition of Zone IV for long term / real time data.	Submitted
3.2.P.8	• Please submit Water loss study data along with calculation sheets and prints of weighing at each interval.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

603.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Private)Ltd (DML # 000946) Khushal Khan Khattak Mazar Road, Akora Khattak, District Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Private)Ltd (DML # 000946) Khushal Khan Khattak Mazar Road, Akora Khattak, District Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New Section granted by CLB
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24776 dated 11-10-2023
	Details of fee submitted	PKR 75,000/-: Dated 18-09-2023 Slip # 381088388435
	The proposed proprietary name /	J-Levo Infusion 500mg/100 ml

	brand name	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100 ml vial contains: Levofloxacin Hemihydrate equivalent to Levofloxacin ……. 500 mg
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotics
	Pharmaceutical form of applied drug	Sterile Solution for injection IV
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	LDPE bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	HPRA Ireland approved formulation in LDPE Bottles
	For generic drugs (me-too status)	Brand Name: Dynaquin Manufacturer: M/s Barrett Hodgson
	Name and address of API manufacturer.	Name: Zhejiang East-Asia Pharmaceutical Co. Ltd. Address: Coastal Industrial City, Pubagang Town, Sanmen county, Zhejiang, China. GMP Validity: 22-12-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 48 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Leflox Infusion **Manufactured by:** Getz **Testing Parameters:** Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	Name: Zhejiang East-Asia Pharmaceutical Co. Ltd. Address: Coastal Industrial City, Pubagang Town, Sanmen county, Zhejiang, China.		
API Lot No.	220929-1		
Description of Pack (Container closure system)	LDPE Bottles		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T- 001	T- 002	T- 003
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	20-01-2023	20-01-2023	20-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Material Loan Giver:** Medicraft Pharmaceuticals, Hayatabad **Quantity:** 400 kg **Invoice:** EXP/225/21-22 **Dated:** 25-11-2022 **Quantity of Loan:** 05kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.P.8	• Please submit Water loss study data along with calculation sheets and prints of weighing at each interval.	Submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

604.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Private)Ltd (DML # 000946) Khushal Khan Khattak Mazar Road, Akora Khattak, District Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Private)Ltd (DML # 000946)

		Khushal Khan Khattak Mazar Road, Akora Khattak, District Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New Section granted by CLB
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22822 dated 18-09-2023
	Details of fee submitted	PKR 30,000/-: Dated 25-10-2022 Slip # 86825268555
	The proposed proprietary name / brand name	J-Para Infusion 100 ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100 ml vial contains: Paracetamol ……. 1000 mg
	Pharmacotherapeutic Group of (API)	Antipyretic
	Pharmaceutical form of applied drug	Sterile Solution for injection IV
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	LDPE bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	HPRA Ireland approved formulation in LDPE Bottles
	For generic drugs (me-too status)	Brand Name: Otsumol infusion Manufacturer: M/s Otsuka
	Name and address of API manufacturer.	Name: Anhui BBCA Likang Pharmaceutical Co. Ltd. Address: High & New Technology Industries Development Zone, Bengbu city, Anhui Province, China. GMP Validity: 19-12-2023
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 48 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Brand Name:** Otsumol infusion **Manufacturer:** M/s Otsuka **Testing Parameters:** Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Anhui BBCA Likang Pharmaceutical Co. Ltd. Address: High & New Technology Industries Development Zone, Bengbu city, Anhui Province, China.		
API Lot No.	202109103A		
Description of Pack (Container closure system)	LDPE Bottles		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	P 001	P 002	P 003
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	22-01-2023	22-01-2023	22-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Material Loan Giver:** Medicraft Pharmaceuticals, Hayatabad **Quantity:** 500 kg **Invoice:** EXP/225/21-22 **Dated:** 02-12-2021 **Quantity of Loan:** 05kg

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

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.P.8	• Please submit Water loss study data along with calculation sheets and prints of weighing at each interval.	Submitted

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

New License remaining: M/s Maxitech Pharma (Pvt) Ltd. (DML # 000851), Karachi.
Dosage form: Soft Gelatin Capsule (General).
Central Licensing Board in its 250th meeting approved the grant of DML # 000851 (Formulation) for the manufacturing facility including Soft Gelatin Capsule (General). 7 molecules have already been considered.

605.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Maxitech Pharma (Pvt) Ltd. (DML # 000851) Plot No. Z-178, S.I.T.E Phase-II, Super Highway, Karachi.**
	Name, address of Manufacturing site.	**M/s Maxitech Pharma (Pvt) Ltd. (DML # 000851) Plot No. Z-178, S.I.T.E Phase-II, Super Highway, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New Section granted by CLB
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 17161 dated 10-07-2023
	Details of fee submitted	PKR 75,000/-: Dated 19-12-2022 Slip # 647740146494
	The proposed proprietary name / brand name	Maxinoin 30 mg Soft Gelatin Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains: Isotretinoin ……. 30 mg
	Pharmacotherapeutic Group of (API)	Retinoids
	Pharmaceutical form of applied drug	Soft Gelatin Capsule
	Reference to Finished product	USP Specification

	specifications	
	Proposed Pack size	3 x 10s, 2 x 10s, 1 x 10s.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TGA Australia approved formulation
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Name: Shanghai New Hualian Pharmaceutical Co. Ltd. Address: 217 MINLE ROAD, SHANGAI, HAIWAN, China. GMP Validity: 31-12-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Accutane Soft Gel Capsule 30 mg **Manufactured by:** JG Pharma **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Name: Shanghai New Hualian Pharmaceutical Co. Ltd. Address: 217 MINLE ROAD, SHANGAI, HAIWAN, China.
API Lot No.	
Description of Pack (Container closure system)	ALU-ALU Blister each containing 10s packed din printed unit carton, further packed in a master carton.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 06 months

	Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TR- 001	TR- 002	TR- 001
Batch Size	1.2KG	1.2KG	1.2KG
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	28-10-2022	28-10-2022	28-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 30 kg **Dated:** 05-07-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.5.11	• Please submit Proposed label [outer (secondary) & inner (primary)] & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens which should mention the signs of precautionary measures / contraindications.	Submitted
1.6.5	• Please submit GMP certificate of API manufacturer issued by regulatory authority of the country of origin which should be valid till date.	Submitted
3.2.P.2	• Please submit complete record of comparative dissolution profile.	Submitted
3.2.P.3	• As isotretinoin is a light sensitive material with high risk of oxidation, please provide details of the arrangement of sodium vapor lamps / other arrangements for opening of bulk container of API to protect from light and air.	Firm has submitted SOP defining the precautionary measures i.e. installation of red light during manufacturing process.
	• Please submit details of precautions during dispensing procedure.	Firm has submitted SOP defining the precautionary measures i.e. installation of red light during dispensing and controlling by contnous nitrogen purging.

	• Submit details of nitrogen purging for Vacuum for full de-aeration during soft gel manufacturing.	Submitted
	• Please submit details of the quantity of bulk container of API isotretinoin procured for manufacturing of the stability batches.	Submitted
	• Please submit evidence of personal protective equipment for the personnel working in manufacturing facility of capsules.	Submitted
	• Please submit BMR along with cleaning validation process and related SOPs for line clearance and QA role in controlling the CQAs for critical process parameters.	Submitted
3.2.P.5	• Please submit details of in process tests for soft gel preparation, bulk solution of API to be filled in capsules, leak tests etc. • Please submit evidence of helium or nitrogen purging required during preparation of diluent for sample preparation for HPLC assay.	Submitted Submitted
	• Please submit the details / pictorial evidence of apparatus arrangement for dissolution method as described in USP Test 1 for dissolution.	Submitted
	• Please submit chromatograms related to system suitability test of HPLC given in USP monograph for isotretinoin capsule.	Submitted
	• Please submit training certificate along with training material, of personnel designated in QC Laboratory to perform testing of drug product and API.	Submitted
3.2.P.8	• Please submit COA of API Lot# used in manufacturing of stability batches.	Submitted
	• Please Submit DRAP clearance documents for procurement of API.	Submitted
	• Please submit complete 06th month stability data for all intervals (0,3 & 6 months).	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

606.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Maxitech Pharma (Pvt) Ltd. (DML # 000851) Plot No. Z-178, S.I.T.E Phase-II, Super Highway, Karachi.**
	Name, address of Manufacturing site.	**M/s Maxitech Pharma (Pvt) Ltd. (DML # 000851) Plot No. Z-178, S.I.T.E Phase-II, Super Highway, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New Section granted by CLB
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	☒ New Drug Product (NDP)

		☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 35338 dated 06-12-2023
	Details of fee submitted	PKR 30,000/-: Dated 04-11-2022 Slip # 79356342176
	The proposed proprietary name / brand name	Cholce-D 200,000 IU Soft Gelatin Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains: Colecalciferol 200,000 IU equivalent to Vitamin D3 ……. 5 mg
	Pharmacotherapeutic Group of (API)	Vitamin D analogs
	Pharmaceutical form of applied drug	Soft Gelatin Capsule
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	3 x 10s, 2 x 10s, 1 x 10s.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Firm explained that Vitamin D3, 200,000 IU formulation is available in SRA countries in ampoule, but in Pakistan 200,000 IU is available in both oral & IM formulation, therefore firm applied 200,000 IU in soft gelatin capsule under the umbrella of Vitamin Policy as the same strength & dosage form is available in market of Pakistan under the enlistment of H&OTC but after vitamin policy, above 10,000 IU cannot be enlisted in H&OTC, as per Vitamin policy below cause *"Those combinations already having registration in Pakistan and marketing proof of availability of 5-7 years in market with no reported adverse reactions, shall be considered as reference for safety & efficacy of these combinations".*
	For generic drugs (me-too status)	In Pakistan, the formulation in same dosage form and strength has been enlisted in Health & OTC Division, DRAP & available in the market of Pakistan.
	Name and address of API manufacturer.	Name: Fermenta Biotech Limited. Address: Plot # Z-109 B & C, SEZ-II, Dahej TAL- VAGRA, City Dahej, Dist. Bharuch, Gujarat, India. GMP Validity: 04-07-2026
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Accelerated stability Data for 6 months.

	(Conditions & duration of Stability studies)	Temperature: 25°C ± 2°C Humidity: 60% ± 5% RH Real time stability data for 36 months. Temperature: 5°C ± 3°C
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Accutane Soft Gel Capsule 30 mg **Manufactured by:** JG Pharma **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Shanghai New Hualian Pharmaceutical Co. Ltd. Address: 217 MINLE ROAD, SHANGAI, HAIWAN, China.		
API Lot No.			
Description of Pack (Container closure system)	ALU-ALU Blister of 1's packed in printed unit carton, further packed in a master carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TR- 001	TR- 002	TR- 003
Batch Size	1.0 KG	1.0 KG	1.0 KG
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	04-2021	04-2021	04-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 1.0 kg **Invoice:** RV2010020281 **Dated:** 16-12-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.1	• Please submit differential fee of PKR 45000/- for the status of your application as "New Drug Application" to be registered as drug product as per Vitamin Policy.	Submitted Challan # 929951095253 Dated : 04-03-2024
1.5.6	• Please submit Pharmacopeia reference / specifications of applied formulation.	USP Specifications
1.5.9	• Please submit evidence of approval of applied formulation in reference regulatory authorities / agencies (USFDA, MHRA, TGA, PMDA, EMA etc.) which were adopted by the Registration Board in its 275th meeting.	Firm explained that Vitamin D3, 200,000 IU formulation is available in SRA countries in ampoule, but in Pakistan 200,000 IU is available in both oral & IM formulation, therefore firm applied 200,000 IU in soft gelatin capsule under the umbrella of Vitamin Policy as the same strength & dosage form is available in market of Pakistan under the enlistment of H&OTC but after vitamin policy, above 10,000 IU cannot be enlisted in H&OTC, as per Vitamin policy below cause *"Those combinations already having registration in Pakistan and marketing proof of availability of 5-7 years in market with no reported adverse reactions, shall be considered as reference for safety & efficacy of these combinations".*
1.5.11	• Please submit Proposed label [outer (secondary) & inner (primary)] & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens which should mention the signs of precautionary measures / contraindications.	Submitted
1.6.5	• Please submit GMP certificate of API manufacturer issued by regulatory authority of the country of origin which should be valid till date.	Submitted
3.2.S.4	• As per Maxitech's COA of API, Please justify that why all tests as per USP specifications have not been performed?	COA submitted with all test performed.
3.2.P.1	• Please justify the use of 5% overage of API in the manufacture of the drug product, whether they appear in the final formulated product or not?	As the trial batch size is small and this is light sensitive material, in order to maintain the label claim in trial batches, overages added and that will be validate through three process validation on commercial baches.
	• Is the use of amount of overage to compensate for expected and documented manufacturing losses?	
3.2.P.3	• As Cholecalciferol is a light sensitive material, please provide details of the arrangement of sodium vapor lamps / other arrangements for opening of bulk container of API to protect from light and air.	Pictorial evidence attached.
	• Please submit details of precautions during dispensing procedure.	Complete dispensing procedrure with precautionary measures submitted.

	• Submit details of nitrogen purging for Vacuum for full de-aeration during soft gel manufacturing.	Submitted
	• Please submit details of the quantity of bulk container of API Cholecalciferol procured for manufacturing of the stability batches.	Submitted
	• Please submit evidence of personal protective equipment for the personnel working in manufacturing facility of capsules.	List of PPE mentioned in manufacturing pocess.
	• Please submit evidence that Maxitech's dispensing area for API has instruments/ equipment to hermetically seal containers under nitrogen after dispensing the required amount of API, installation of sodium vapor lamp to confirm the area free from UV radiations.	Firm explained that they closed the pouch in the container immediately after dispensing if leftover remains.
	• Please submit BMR along with cleaning validation process and related SOPs for line clearance and QA role in controlling the CQAs for critical process parameters.	Submitted
	• In section 3.2.P.3.3, please revise "General compliance conditions" of manufacturing area as per the safety parameters / conditions defined under Material safety data sheet for Cholecalciferol.	Submitted
3.2.P.5	• Please submit details of in process tests for Gelatin mass preparation, fill liquid preparation, encapsulation, drying, polishing and packaging, leak tests etc.	Submitted
	Please submit chromatograms related to system suitability test of HPLC given in USP monograph for Cholecalciferol capsule.	Submitted
	• Please submit evidence of nitrogen purging required during preparation of standard solution B for HPLC assay.	Submitted
	• Please submit training certificate along with training material, of personnel designated in QC Laboratory to perform testing of drug product and API.	Submitted
	• Please revise the formula of calculation of assay as per the parameters defined in the USP monograph.	Submitted
3.2.P.8	• Please submit COA of API Lot# used in manufacturing of stability batches.	Submitted
	• Please Submit DRAP clearance documents for procurement of API.	Submitted
	• Please submit chromatograms along with calculation sheets for content uniformity test as per USP Specifications.	Submitted

Decision: Deferred for the evidence of RRA

New License

Central Licensing Board in its 250th meeting, approved the grant of Drug Manufacturing License (DML) to M/s Cortex Pharmaceuticals (DML # 000826), Rawat for External Liquid Preparation (General). 09 out of ten (10) products of External Liquid Preparation have already been considered, and 10th product application is mentioned below.

607.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cortex Pharmaceuticals (DML # 000826)** **Plot no.16-A, SS-4,National Industrial Zone, Rawat, Islamabad.**
	Name, address of Manufacturing site.	M/s Cortex Pharmaceuticals (DML # 000826) Plot no.16-A, Ss-4,National Industrial Zone, Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate of the firm issued on the basis of inspection report dated 12-02-2021.
	Evidence of approval of manufacturing facility	New License
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. V7V-1TM-77M9d Dated 08-12-2023
	Details of fee submitted	PKR 30,000/-: Dated 26-09-2023 Slip # 5802947489
	The proposed proprietary name / brand name	Calamox (Calamine) Topical Lotion USP
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100 ml contains: Calamine..... 8 g Zinc Oxide..... 8 g
	Pharmaco-therapeutic Group of (API)	Skin Protectant
	Pharmaceutical form of applied drug	Topical lotion
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	60 ml & 120 ml PET bottles
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TGA Australia approved formulation
	For generic drugs (me-too status)	Calamine Lition by Jawa Pharma (Reg. # 004712)
	Name and address of API manufacturer.	**<u>Zinc Oxide</u>** Name: Anmol Chemical Private Limited Address: J-63 Road No. U-6, MIDC, Taloja, District Raigad Zone1, India. GLP validity: 28-09-2023 **<u>Calamine</u>** Name: Mehta Pharmaceutical Industries Address: UNIT NO II KOPRI VILLAGE NAKA, VIRAR (E) DIST. PALAGHAR, INDIA. GMP validity : 28-09-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical

		procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Calamine** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 54 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH **Zinc Oxide** Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Calamine Lotion **Manufactured by:** Jawa Pharma. **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Zinc Oxide** Name: Anmol Chemical Private Limited Address: J-63 Road No. U-6, MIDC, Taloja, District Raigad Zone1, India. GLP validity: 28-09-2023 **Calamine** Name: Mehta Pharmaceutical Industries Address: UNIT NO II KOPRI VILLAGE NAKA, VIRAR (E) DIST. PALAGHAR, INDIA. GMP validity : 28-09-2024	
API Lot No.	**Calamine**	**Zinc oxide**
	CAL/37/2022	AC/23070824
Description of Pack (Container closure system)	Pink color viscous lotion packed in 120 ml dropper further packed in Bleech Card Unit Carton along with Leaflet	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period	Real time: 06 months Accelerated: 06 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)	

Batch No.	T-001	T-002	T-003
Batch Size	5 Liter	5 Liter	5 Liter
Manufacturing Date	16 -01-2023	16 -01-2023	16 -01-2023
Date of Initiation	16-01-2023	16-01-2023	16-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Material Loan:** Jawa Pharma Calamine: 1.5 kg Zinc Oxide: 1.5 kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not required
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

New License

Central Licensing Board in its 284th meeting held on 16th December 2021, approved the grant of Drug Manufacturing License (DML) to M/s Wallace Pharma Evolution (DML # 000951), Lahore including Injection (Carbapenem) Section.

608.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolution (DML # 000951) Kala Wala Stop, 20-km Lahore Jaranwala Road.**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution (DML # 000951) Kala Wala Stop, 20-km Lahore Jaranwala Road.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New License
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 314-L7X-7EP1 Dated 27-03-2024

	Details of fee submitted	PKR 75000/-: Dated 17-02-2024 Slip # 07017162806
	The proposed proprietary name / brand name	Meronim 2 G Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate) ..... 2 g (Blended with sodium carbonate)
	Pharmaco-therapeutic Group of (API)	Carbapenem Antibiotics
	Pharmaceutical form of applied drug	Sterile Powder for injection
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	***Meropenem with Sodium Carbonate*** **CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.** **Address**: No. 88 Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, Hebei Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Innovator brand **Manufactured by:** ***not provided*** **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	**CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd. Address**: No. 88 Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, Hebei Province, China.		
API Lot No.	***Not provided***		
Description of Pack (Container closure system)	White to off White Color Sterile Powder filled in Type I glass vial.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	M-07	M-08	M-09
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	17-04-2022	17-04-2022	17-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.S.4	• Please provided the details of pre-mix ratio in grams of sodium carbonate and Meropenem salt and base.	Submitted
3.2.P.2	• Please provide Brand name, Batch #, Manufacturer name, receipt of date of purchase of brand for performance of Pharmaceutical equivalence.	Submitted
3.2.P.8	• Please submit documents for Procurement of API approved by DRAP.	Submitted
	• Please submit COA of API used in manufacturing of stability batches.	Submitted
	• Please submit data regarding assay of sodium content.	Submitted
	• Please submit inspection report issued by DRAP for the evidence for availability of Atomic absorption spectroscopy in your firm.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

New License

Central Licensing Board in its 293rd meeting held on 20th November 2023, approved the grant of Drug Manufacturing License (DML) to M/s Misaq Pharmaceutical Pvt. Ltd. (DML # 000985), for following section.

External Liquid Section (Povidone Iodine only)

609.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Misaq Pharmaceutical Pvt. Ltd. (DML # 000985)** **Plot No. 7-B, Woven Garments Zone, Value Addition City, Khurrianwala, Sahianwala Road, Faisalabad**
	Name, address of Manufacturing site.	M/s Misaq Pharmaceutical Pvt. Ltd. (DML # 000985) Plot No. 7-B, Woven Garments Zone, Value Addition City, Khurrianwala, Sahianwala Road, Faisalabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New License
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. ZSZ-TYW-N7VT Dated 17-04-2024
	Details of fee submitted	PKR 30000/-: Dated 01-03-2024 Slip # 177082724679
	The proposed proprietary name / brand name	Miodine 7.5% Solution
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Contains: - Povidone Iodine 75mg equivalent to Available Iodine …… 7.5mg
	Pharmaco-therapeutic Group of (API)	Antiseptic, germicidal
	Pharmaceutical form of applied drug	Topical Surgical Scrub solution
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	C-Pyidine Scrub Care 7.5 by Cortex Pharma
	Name and address of API manufacturer.	**M/s Caliber Chemicals Pvt. Ltd.** **Address:** Plot No. 901/A, 901/B, 903, 905, 907, 1002, 1004, & 1006, GIDC Sarigam, Tal, Umbergaon, Sarigam, Valsad, Gujrat India. GMP Validity: 12-06-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general

		properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Pyidine 7.5% **Manufactured by:** Cortex Pharma **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**M/s Caliber Chemicals Pvt. Ltd.** **Address:** Plot No. 901/A, 901/B, 903, 905, 907, 1002, 1004, & 1006, GIDC Sarigam, Tal, Umbergaon, Sarigam, Valsad, Gujrat India.		
API Lot No.	PVI-G-500		
Description of Pack (Container closure system)	Brownish colored solution filled in 60ml pet bottle with cap.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TRS-PV1-001	TRS-PV1-002	TRS-PV1-003
Batch Size	100 Bottles (60ml)	100 Bottles (60ml)	100 Bottles (60ml)
Manufacturing Date	08-2023	08-2023	08-2023
Date of Initiation	31-08-2023	31-08-2023	31-08-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Material loan from Kohinoor Industries **Quantity:** 2 kg **Dated:** 10-08-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not required
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

610.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Misaq Pharmaceutical Pvt. Ltd. (DML # 000985)** **Plot No. 7-B, Woven Garments Zone, Value Addition City, Khurrianwala, Sahianwala Road, Faisalabad**
	Name, address of Manufacturing site.	M/s Misaq Pharmaceutical Pvt. Ltd. (DML # 000985) Plot No. 7-B, Woven Garments Zone, Value Addition City, Khurrianwala, Sahianwala Road, Faisalabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New License
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. RHW-DM5-RDYV Dated 17-04-2024
	Details of fee submitted	PKR 30000/-: Dated 01-03-2024 Slip # 3739862170
	The proposed proprietary name / brand name	Miodine 10% Solution
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Contains: - Povidone Iodine 100mg equivalent to Available Iodine ..... 10 mg
	Pharmaco-therapeutic Group of (API)	Antiseptic, germicidal
	Pharmaceutical form of applied drug	Topical solution

	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Pyodine 10% Solution by Brookes Pharma
	Name and address of API manufacturer.	**M/s Caliber Chemicals Pvt. Ltd.** **Address:** Plot No. 901/A, 901/B, 903, 905, 907, 1002, 1004, & 1006, GIDC Sarigam, Tal, Umbergaon, Sarigam, Valsad, Gujrat India. GMP Validity: 12-06-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Pyodine 10% **Manufactured by:** Broookes Pharma **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**M/s Caliber Chemicals Pvt. Ltd.** **Address:** Plot No. 901/A, 901/B, 903, 905, 907, 1002, 1004, & 1006, GIDC Sarigam, Tal, Umbergaon, Sarigam, Valsad, Gujrat India.
API Lot No.	PVI-G-500
Description of Pack (Container closure system)	Brownish colored solution filled in 60ml pet bottle with cap.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 06 months

	Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TRS-P10-001	TRS-P10-002	TRS-10-003
Batch Size	100 Bottles (60ml)	100 Bottles (60ml)	100 Bottles (60ml)
Manufacturing Date	08-2023	08-2023	08-2023
Date of Initiation	31-08-2023	31-08-2023	31-08-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Material loan from Kohinoor Industries **Quantity:** 2 kg **Dated:** 10-08-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not required
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

New License

Central Licensing Board in its 286th meeting held on 11th May 2022, approved the grant of Drug Manufacturing License (DML) to M/s Pharman Pharmaceuticals Pvt. Ltd. (DML # 000958), including Oral Liquid Section (General)

611.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharman Pharmaceuticals Pvt. Ltd. (DML # 000958) Khewat # 59, Khatooni # 114-120, Tehsil Wazirabad, Dist. Gujaranwala.**
	Name, address of Manufacturing site.	**M/s Pharman Pharmaceuticals Pvt. Ltd. (DML # 000958) Khewat # 59, Khatooni # 114-120, Tehsil Wazirabad, Dist. Gujaranwala.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New License
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. GAU-7G2-U3EX Dated 25-03-2024
	Details of fee submitted	PKR 30000/-: Dated 01-03-2024 Slip # 699686854625
	The proposed proprietary name / brand name	Cetirizine Syrup
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml Contains: - Cetirizine dihydrochloride …….. 5mg
	Pharmaco-therapeutic Group of (API)	Antihistamine ATC Code: S01GX12
	Pharmaceutical form of applied drug	Oral Liquid
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	30ml, 60ml, 90ml, 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Rigix Syrup by AGP
	Name and address of API manufacturer.	**Name:** Sreekara Organics **Address:** Plot No. 159/A, S.V. Co-op. Ind. Estate, IDA Bollaram, Jinnaram (M),Sangareddy Dist-502325, Telangana, India GMP Validity: 24-04-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 25°C ± 2°C / 60% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Zyrtec Oral Solution **Manufactured by:** GSK **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Name:** Sreekara Organics **Address:** Plot No. 159/A, S.V. Co-op. Ind. Estate, IDA Bollaram, Jinnaram (M),Sangareddy Dist-502325, Telangana, India		
API Lot No.	CTZ08721		
Description of Pack (Container closure system)	Colorless and Banana flavor syrup filled in amber glass bottle		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	CZ22-01	CZ22-002	CZ22-03
Batch Size	60 Litres	60 Litres	60 Litres
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	15-12-2022	15-12-2022	15-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Material loan from Batala Pharmaceuticals **Quantity:** 3 kg **Dated:** 29-04-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Secction	Observations	Status
3.2.S.7	Please submit stability data of APi as per conditions of Zone IVA or Zone IV-B as per climatic conditions of Pakistan.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

612.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharman Pharmaceuticals Pvt. Ltd. (DML # 000958) Khewat # 59, Khatooni # 114-120, Tehsil Wazirabad, Dist. Gujaranwala.**
	Name, address of Manufacturing site.	M/s Pharman Pharmaceuticals Pvt. Ltd. (DML # 000958) Khewat # 59, Khatooni # 114-120, Tehsil Wazirabad, Dist. Gujaranwala.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New License
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. XQU-ZZU-A7NM Dated 25-03-2024
	Details of fee submitted	PKR 30000/-: Dated 01-03-2024 Slip # 9425973001
	The proposed proprietary name / brand name	Parasol Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml Contains: - Paracetamol …… 120 mg
	Pharmaco-therapeutic Group of (API)	Analgesics and Antipyretic. ATC Code: N02BE01
	Pharmaceutical form of applied drug	Oral Suspension
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	30ml, 60ml, 90ml, 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Calpol by GSK
	Name and address of API manufacturer.	**Name:** CITI Pharma Limited **Address:** 3.5 KM, HEAD BALOKI ROAD, PHOOL NAGAR, KASUR PAKISTAN
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls,

		specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Panadol Suspension **Manufactured by:** GSK **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Name:** CITI Pharma Limited **Address:** 3.5 KM, HEAD BALOKI ROAD, PHOOL NAGAR, KASUR PAKISTAN		
API Lot No.	PGP22-295 *(Paracetamol micronized)*		
Description of Pack (Container closure system)	Parasol Suspension are packed in plastic bottle with plastic cap, further packed in unit carton along with patient leaflet insert		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	PC22-001	PC22-002	PC22-003
Batch Size	120 Litres	120 Litres	120 Litres
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	13-10-2022	13-10-2022	13-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Local procurement
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

New Section

Central Licensing Board in its 270th meeting held on 23rd May 2019, approved the grant of Drug Manufacturing License (DML) to M/s Metro Pharmaceuticals Pvt. Ltd. (DML # 000772), for additional sections including Sterile Powder Vials (Cepalosporin) Section.

613.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Metro Pharmaceuticals Pvt. Ltd. (DML # 000772) Plot no 14, street no SS-2, Industrial Zone Rawat Islamabad.**
	Name, address of Manufacturing site.	**M/s Metro Pharmaceuticals Pvt. Ltd. (DML # 000772) Plot no 14, street no SS-2, Industrial Zone Rawat Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New License
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. DJT-VLB-ZZMB Dated 06-03-2024
	Details of fee submitted	PKR 30000/-: Dated 25-01-2024 Slip # 96601457644
	The proposed proprietary name / brand name	Getzone 1 gm Injection IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial Contains: - Ceftriaxone Sodium equivalent to Ceftriaxone …….. 1 gm
	Pharmaco-therapeutic Group of (API)	Cephalosporins
	Pharmaceutical form of applied drug	Sterile Powder for reconstitution for IV injection
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Oxidil by Sami Pharma

	Name and address of API manufacturer.	**Name:** Zhuhai United Laboratories Co. Limited **Address:** No. 2428, Ajiroad Sanzao Town, Jinan District, Zhuhai Guangdong, China. GMP Validity: 05-12-2023
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Rocephin 1 gram injection **Manufactured by:** Martin Dow **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Name:** Zhuhai United Laboratories Co. Limited **Address:** No. 2428, Ajiroad Sanzao Town, Jinan District, Zhuhai Guangdong, China.		
API Lot No.	3052206025		
Description of Pack (Container closure system)	Colorless and Banana flavor syrup filled in amber glass bottle		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TR-INJ-001	TR-INJ-002	TR-INJ-003
Batch Size	500 Vials	500 Vials	500 Vials
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	26-12-2022	26-12-2022	26-12-2022

No. of Batches	03

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Material loan from Hi-Medic Pharmaceuticals **Quantity:** 10 kg **Dated:** 23-11-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Secction	Observations	Status
3.2.S.7	Please submit stability data of APi as per conditions of Zone IVA or Zone IV-B as per climatic conditions of Pakistan.	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

New Section

Central Licensing Board in its 270th meeting held on 23rd May 2019, approved the grant of Drug Manufacturing License (DML) to M/s Metro Pharmaceuticals Pvt. Ltd. (DML # 000772), for additional sections including Capsule (Cepalosporin) Section.

614.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Metro Pharmaceuticals Pvt. Ltd. (DML # 000772) Plot no 14, street no SS-2, Industrial Zone Rawat Islamabad.**
	Name, address of Manufacturing site.	**M/s Metro Pharmaceuticals Pvt. Ltd. (DML # 000772) Plot no 14, street no SS-2, Industrial Zone Rawat Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New License
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. SMG-Y7V-QT32 Dated 06-03-2024
	Details of fee submitted	PKR 30000/-: Dated 25-01-2024 Slip # 01566705845

	The proposed proprietary name / brand name	Zigam 400 mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial Contains: - Cefixime (as trihydrate) …… 400 mg
	Pharmaco-therapeutic Group of (API)	Cephalosporins
	Pharmaceutical form of applied drug	Oral hard gelatin capsule
	Reference to Finished product specifications	DRAP's Specifications
	Proposed Pack size	5s, 10s, & 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Cefiget by Opal
	Name and address of API manufacturer.	**Name:** CITI Pharma Limited **Address:** 3.5 KM, HEAD BALOKI ROAD, PHOOL NAGAR, KASUR PAKISTAN
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Cefiget Capsule 400 mg **Manufactured by:** Opal Laboratories **Testing Parameters:** DRAP's Specifications **Comparative Dissolution Profile:** similarity beteen reference and manufacturer's product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	**Name:** CITI Pharma Limited **Address:** 3.5 KM, HEAD BALOKI ROAD, PHOOL NAGAR, KASUR PAKISTAN		
API Lot No.	CFM2201015		
Description of Pack (Container closure system)	1 x 5s capsules packed in ALU ALU blisters		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TBC- 001	TBC- 002	TBC- 003
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	27-12-2022	27-12-2022	27-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Locally procured
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved as per the DRAP specification vide letter No. F. 14-1/2022 dated 14th March, 2022

New Section

Central Licensing Board in its 277th meeting held on 15th – 16th October 2020, approved the grant of Drug Manufacturing License (DML) to M/s Ferozsons Pharmaceuticals Pvt. Ltd. (DML # 000038), for additional section Cream /Ointment/Gel (Steroid).

615.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Limited (DML # 000038) Amangarh, Nowshera, Khyber Pakhtunkhwa.**
	Name, address of Manufacturing site.	**M/s Ferozsons Laboratories Limited (DML # 000038) Amangarh, Nowshera, Khyber Pakhtunkhwa.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Validity : 14-06-205
	Evidence of approval of	New Section

	manufacturing facility	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. RV6-M8V-85ND Dated 09-02-2024
	Details of fee submitted	PKR 30000/-: Dated 18-01-2024 Slip # 14110740969
	The proposed proprietary name / brand name	Cutica Cream 0.05%
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of Cream Contains: - Fluticasone Propionate (micronised) …… 0.5 mg (0.05% w/w)
	Pharmaco-therapeutic Group of (API)	Corticosteroid
	Pharmaceutical form of applied drug	Topical cream
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	5g, 10g, 15g, 30g & 50g
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Cutivate Cream by GSK
	Name and address of API manufacturer.	**Name :** Aurisco Pharmaceutical Co., Ltd - China **Address :** Badu Industrial Park Zone, Tiantai County, Zhejiang Province 317200 P.R China GMP Validity:
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications,

		analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Cutivate cream **Manufactured by:** GSK **Testing Parameters:** BP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Name :** Aurisco Pharmaceutical Co., Ltd - China **Address :** Badu Industrial Park Zone, Tiantai County, Zhejiang Province 317200 P.R China		
API Lot No.	AF-B-210501 &		
Description of Pack (Container closure system)	Single 10 grams aluminium collapsible tube is packed ina cardboard box.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 24 (Months)		
Batch No.	338NS12	338NS13	338NS14
Batch Size	350 grams	350 grams	350 grams
Manufacturing Date	06-2023	06-2023	06-2023
Date of Initiation	24-06-2023	24-06-2023	24-06-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 34 grams **Dated :** 23-08-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

New License

Central Licensing Board in its 292nd meeting held on 04th October 2023, approved the grant of Drug Manufacturing License (DML) to M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd (DML # 000986), including

i. Oral Dry Powder for Suspension (Cephalosporin).
ii. Capsule (Cephalosporin) Section
iii. Tablet (General) Section
iv. Injection Ampoule (General) Section.

616.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd (DML # 000986) Plot No. 95-A, , Industrial Estate KLP Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd (DML # 000986) Plot No. 95-A, , Industrial Estate KLP Road, Rahim Yar Khan.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New License
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. SEQ-WMX-99NQ Dated 22-04-2024
	Details of fee submitted	PKR 30000/-: Dated 18-04-2024 Slip # 8345618127
	The proposed proprietary name / brand name	Muracef 125mg/5ml Dry Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml of reconstituted Suspension contains: - Cefadroxil Monohydrate equivalent to Cefadroxil …… 125 mg
	Pharmaco-therapeutic Group of (API)	Cephalosporin
	Pharmaceutical form of applied drug	Oral Powder for reconsitution
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Biodroxil 125mg/5ml by Sandoz GMBH, Austria Listed in European Medicine Agency (EMA)
	For generic drugs (me-too status)	Sephidrox by Seraph Pharma
	Name and address of API manufacturer.	**Name:** M/S Pharmagen Limited **Address:** 34-Km, Ferozepur Road, Lahore, Pakistan. GMP Validity: compliant
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general

		properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Sephidrox 250mg/5ml Dry Suspension **Manufactured by:** Seraph Pharmaceuticals **Testing Parameters:** USP Specifications **Comparative Dissolution Profile:** similarity between reference and manufacturer's product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Name:** M/S Pharmagen Limited **Address:** 34-Km, Ferozepur Road, Lahore, Pakistan.		
API Lot No.	002240/23-09/014		
Description of Pack (Container closure system)	White colored powder filledin Glass Bottle Dry Suspensions		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 24 (Months)		
Batch No.	T001	T002	T003
Batch Size	600 Bottles	600 Bottles	600 Bottles
Manufacturing Date	11-2023	11-2023	11-2023
Date of Initiation	08-11-2023	08-11-2023	08-11-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Locally procured
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations
3.2.P.8	Please submit the stability data for the 06th month for both accelerated and real time conditions.

Decision: Approved. The registration letter shall be issued after submission of 6th month stability data by the firm.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

617.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd (DML # 000986) Plot No. 95-A, , Industrial Estate KLP Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd (DML # 000986) Plot No. 95-A, , Industrial Estate KLP Road, Rahim Yar Khan.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New License
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. RV6-M8V-85ND Dated 09-02-2024
	Details of fee submitted	PKR 30000/-: Dated 18-01-2024 Slip # 14110740969
	The proposed proprietary name / brand name	Muracef 250mg/5ml Dry Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml of reconstituted Suspension contains: - Cefadroxil Monohydrate equivalent to Cefadroxil …… 250 mg
	Pharmaco-therapeutic Group of (API)	Cephalosporin
	Pharmaceutical form of applied drug	Oral Powder for reconsitution
	Reference to Finished product	USP Specifications

	specifications	
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Sephidrox by Seraph Pharma
	Name and address of API manufacturer.	**Name:** M/S Pharmagen Limited **Address:** 34-Km, Ferozepur Road, Lahore, Pakistan. GMP Validity: compliant
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Sephidrox 250mg/5ml Dry Suspension **Manufactured by:** Seraph Pharmaceuticals **Testing Parameters:** USP Specifications **Comparative Dissolution Profile:** similarity between reference and manufacturer's product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/S Pharmagen Limited **Address:** 34-Km, Ferozepur Road, Lahore, Pakistan.
API Lot No.	002240/23-09/014
Description of Pack (Container closure system)	White colored powder filledin Glass Bottle Dry Suspensions
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 24 (Months)		
Batch No.	T001	T002	T003
Batch Size	600 Bottles	600 Bottles	600 Bottles
Manufacturing Date	11-2023	11-2023	11-2023
Date of Initiation	08-11-2023	08-11-2023	08-11-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Locally procured
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations
3.2.P.8	Please submit the stability data for the 06th month for both accelerated and real time conditions.

Decision: Approved. The registration letter shall be issued after submission of 6th month stability data by the firm.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

618.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd (DML # 000986) Plot No. 95-A, , Industrial Estate KLP Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd (DML # 000986) Plot No. 95-A, , Industrial Estate KLP Road, Rahim Yar Khan.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New License
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. Z98-BD5-9TZU Dated 22-04-2024

	Details of fee submitted	PKR 30000/-: Dated 18-04-2024 Slip # 7507664146
	The proposed proprietary name / brand name	Muracef capsule 500 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: - Cefadroxil Monohydrate equivalent to Cefadroxil …… 500 mg
	Pharmaco-therapeutic Group of (API)	Cephalosporin
	Pharmaceutical form of applied drug	Oral Hard gelatin capsule
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Sephidrox 500 mg Capsules by Seraph Pharma
	Name and address of API manufacturer.	**Name:** M/S Pharmagen Limited **Address:** 34-Km, Ferozepur Road, Lahore, Pakistan. GMP Validity: compliant
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Sephidrox 500 mg capsule **Manufactured by:** Seraph Pharmaceuticals **Testing Parameters:** USP Specifications **Comparative Dissolution Profile:** similarity between reference and manufacturer's product.

	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/S Pharmagen Limited **Address:** 34-Km, Ferozepur Road, Lahore, Pakistan.		
API Lot No.	00510931/468/2023		
Description of Pack (Container closure system)	Alu-Alu blisters in bleach card unit carton along with leaflet		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 24 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 capsule	1500 capsule	1500 capsule
Manufacturing Date	11-2023	11-2023	11-2023
Date of Initiation	09-11-2023	09-11-2023	09-11-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Locally procured
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations
3.2.P.8	Please submit the stability data for the last interval (06th month) for both accelerated and real time conditions.

Decision: Approved. The registration letter shall be issued after submission of 6th month stability data by the firm.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

619.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd (DML # 000986) Plot No. 95-A, , Industrial Estate KLP Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd (DML # 000986) Plot No. 95-A, , Industrial Estate KLP Road, Rahim Yar Khan.**

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New License
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. JWL-EV2-16AJ Dated 22-04-2024
	Details of fee submitted	PKR 30000/-: Dated 03-04-2024 Slip # 208287200
	The proposed proprietary name / brand name	AQUA-NM Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each glass ampoule contains: - Sterile Water for Injection …… 5 ml
	Pharmaco-therapeutic Group of (API)	Diluent
	Pharmaceutical form of applied drug	Sterile water for injection
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Localy registered
	Name and address of API manufacturer.	Not required *(self manufacturing)*
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Not required

	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** WFI **Manufactured by:** GSK **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Self-Manufacturing		
API Lot No.	Not required		
Description of Pack (Container closure system)	Clear colorless & odorless liquid filled in clear glass ampoules.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 24 (Months)		
Batch No.	WN001	WN002	WN003
Batch Size	500 Ampoules	500 Ampoules	500 Ampoules
Manufacturing Date	10-2023	10-2023	10-2023
Date of Initiation	02-10-2023	02-10-2023	02-10-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Self-manufacturing
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Self-manufacturing
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not required
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
620.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd (DML # 000986) Plot No. 95-A, , Industrial Estate KLP Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd (DML # 000986) Plot No. 95-A, , Industrial Estate KLP Road, Rahim Yar Khan.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New License
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. V64-T6Y-B71P Dated 22-04-2024
	Details of fee submitted	PKR 30000/-: Dated 19-04-2024 Slip # 4743466215
	The proposed proprietary name / brand name	Naemol 500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: - Paracetamol …… 500 mg
	Pharmaco-therapeutic Group of (API)	Antipyretic
	Pharmaceutical form of applied drug	Oral Tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Panadol by GSK
	Name and address of API manufacturer.	**Name:** M/S Pharmagen Limited **Address:** 34-Km, Ferozepur Road, Lahore, Pakistan. GMP Validity: compliant
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form,

		manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 36 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Tablet Panadol **Manufactured by:** GSK **Testing Parameters:** USP Specifications **Comparative Dissolution Profile:** similarity between reference and manufacturer's product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/S Pharmagen Limited **Address:** 34-Km, Ferozepur Road, Lahore, Pakistan.		
API Lot No.	002230/23-09/014		
Description of Pack (Container closure system)	White color Round uncoated tabs are blistered in alu-alu blister. Blisters are packed in card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 24 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	10-2023	10-2023	10-2023
Date of Initiation	02-10-2023	02-10-2023	02-10-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Locally procured
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Item No. 03: Priority applications of Short Molecules:

621.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd** **Address: Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore, Pakistan**
	Details of Drug Sale License of importer	License No: 05-352-0065-016174D Address: Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore, Pakistan. Address of Godown: NA Validity: 06.02.2024 Status: **VALID**
	Name and address of marketing authorization holder (abroad)	**PT. NOVELL PHARMACEUTICAL LABORATORIES** Jl. Wanaherang No. 35, Tlajung Udik, Gunung Putri, BOGOR 16962 - **INDONESIA**
	Name, address of manufacturer(s)	**PT. NOVELL PHARMACEUTICAL LABORATORIES** Jl. Wanaherang No. 35, Kelurahan Tlajung Udik, Kecamatan Gunung Putri, Kabupaten Bogor, Provinsi Jawa Barat - **INDONESIA**
	Name of exporting country	**INDONESIA**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Original & Legalized** **Date of Legalization:** 06th July 2023 • **CoPP:** Firm has submitted original, legalized CoPP certificate (No. RG.01.05.32.321.11.23.5302) dated 06-11-2023 issued by National Agency of Drug and Food Control, Jl. Percetakan Negara No. 23, JAKARTA - INDONESIA. The CoPP specifies free sale status of the product in country of export along with its availability. CoPP Validity: 06-11-2025 • **GMP:** The firm has also submitted Original legalized GMP No. : PW-S.01.04.1.3.331.01.22-0012,Valid from 03-01-2022 to 20-12-2026.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from **PT. Novell Pharmaceutical Laboratories, Jl. Pos Pengumben Raya No. 8, Kebon Jeruk, Jakarta Barat – Indonesia.** The letter certifies that "M/s Himmel Pharmaceuticals (Pvt.) Ltd," with address "Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore" is their exclusive agent to register and market "**Norevell (Sevoflurane 100%) Inhalation Vapour, Liquid 250 mL**" in the territory of Pakistan. The letter was issued on 13.11.2023.

	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. L6B-263-9W9W Dated: 05th December 2023
	Details of fee submitted	PKR 150000/-: 23rd June 2023 Slip # 731600620
	The proposed proprietary name / brand name	Norevell (Sevoflurane 100%) Inhalation Vapour, Liquid 250 ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 250ml amber glass bottle contains Sevoflurane ……..100% (v/v)
	Pharmaceutical form of applied drug	Inhalation vapour; liquid
	Pharmacotherapeutic Group of (API)	Anaesthetics, general - ATC code: N01A
	Reference to Finished product specifications	In-house Specification
	Proposed Pack size	250 mL Type III amber glass bottle, closed using phenolic cap and yellow bottle collar.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Sevorane by Getz Pharma
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Name:** Shandong New Time Pharmaceutical Co., Ltd. **Address:** No. 1, North Outer Ring Road, Feixian County, Shandong Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 40 ± 5°C / RH 75% for 06 months. **Real time:** 25 ± 5°C / RH 60% for 36 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Name:** Sevoflurane Baxter **Manufacturer**: Baxter Healthcare of Puerto Rico
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Sevoflurane 100% Inhalation Vapour, Liquid is proposed to be marketed in 250 mL Type III amber glass bottle, closed using phenolic cap and yellow bottle collar. The bottle will be further sealed with shrink seal, labeled with label sticker then packed in unit box accompanied by leaflet.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 40^{o}C ±2^{o}C **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 36 months **Temperature:** 30^{o}C ±2^{o}C **Relative Humidity:** 75% ± 5%. **In use Stability** *(after opening):* 56 days
Evaluation by PEC: • Firm has to submit in hard copy, the legalized documents in original for CoPP, GMP Certificate of exporter & letter of authorization.		
Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad and verification of local storage facility. • **Firm will submit original legalized CoPP & letter of authorization**		
622.	**Import cases**	
	Name, address of Applicant / Importer	**Alpha Evolution enterprises (Pvt.) Ltd** **Office No. 306, 4th floor, Magnum Arcade, E11/2, Islamabad Pakistan.**
	Details of Drug Sale License of importer	License No: DSL-768-ICT/2013 Address: Office No. 306, 4th floor, Magnum Arcade, E11/2, Islamabad Pakistan Address of godown: Shop # 02 & 06, Secon Hills, Northern Strip Markaz, e-11/2, Islamabad. Validity: 11-10-2023 Status: Expired
	Name and address of marketing authorization holder (abroad)	Joint Stock Company "FARMAK" Address: 63, Kyrylivska Street, Kyiv, 04080 Ukraine.
	Name, address of manufacturer(s)	Name: Joint Stock Company "FARMAK"

		Address: 74, Kyrylivska St., Kyiv, 04080, Ukraine; 4, Chornomorska St., Kyiv, 04080, Ukraine.
	Name of exporting country	Ukraine
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**<u>Original & Legalized</u>** **Date of Legalization:** 28th November 2023 • **CoPP:** Firm has submitted original, apostilled CoPP certificate (No. CPP/UA/270/23) dated 12-12-2023 issued by State Service of Ukraine on Medicines and Drugs Control (SMDC). The CoPP specifies free sale status of the product in country of export along with its availability. • **GMP Certificate #** No. 084/2023/GMP**:** ✓ Issued on 19-10-2023 ✓ Validity: 02 years from date of issuance. ✓ Certificate confirms that drug manufacturer complies with the requirement of GMP.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization/Power of Attorney certificate from FARMAK FZ LLC, with its registered office at Dubai Science Park (DSP) Towers – North, Ninth floor, 909N, Dubai, UAE. License No: 98890 Date of Authorization: 29-08-2023 Details of entity authorized in Pakistan: Alpha Evolution Enterprises (Pvt.) Ltd. Head Office Address: Suite No. 306, 4th floor, Magnum Arcade, E/11-2, Islamabad.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 47G-N5B-31J7 Dated: 27th December 2023
	Details of fee submitted	PKR 150000/-: 26th December 2023 Slip # 28339072
	The proposed proprietary name / brand name	Tomohexol 350mgI/ml solution for injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 50 ml vial contains: Iohexol……755mg/ml (755mg Iohexol equivalent to 350mg I)
	Pharmaceutical form of applied drug	Sterile Solution for injection
	Pharmacotherapeutic Group of (API)	Iodinated x-ray contrast media
	Reference to Finished product specifications	Ph. Eur. Specification

	Proposed Pack size	50 ml glass vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	OMNIPAQUE 350mgI/ml, MHRA approved formulation
	For generic drugs (me-too status)	OMNIPAQUE 350mgI/ml (Reg. # 8868)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Name:** Zhejiang Starry Pharmaceutical Co., Ltd. **Address:** No.1 Starry Road of Xianju Modern Industrial Centralization Zone China-317 300 Xianju, Zhejiang Province
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 40º ±2 º C/75 ± 5% RH for 06 months. **Real time:** 25º ±2 º C/60 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Name:** OMNIPAQUE™ (other name ACCUPAQUE™) **Manufacturer**: GE Healthcare, Norway.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	50 mL in the glass bottle (SGD), 32 mm stopper (West), aluminium seal with a plastic cap (Datwyler).
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches with manufacturing date 11/2022 **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 40ºC ±2ºC **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 36 months **Temperature:** 25ºC ±2ºC **Relative Humidity:** 60% ± 5%.

		Conclusions Based on the results of the long-term and accelerated stability studies of the drug product, no significant changes in critical quality attributes of the finished drug product were observed. The study results are provided in Section 3.2.P.8.3. The results of the stress testing of the developed product are provided in Section 3.2.P.5.3. Based on the obtained results, the following storage conditions of the drug product were set: The drug product does not require any special temperature storage conditions. Store containers in the original package to protect from light. A proposed shelf life of the drug product is 2 years.

Evaluation by PEC:

S#	Observations	Reply of the firm
i.	Certificate of pharmaceutical product on WHO format with pack sizes/volume per pack.	Submitted
ii.	The stability data submitted for ZONE IV-A, is for 09 months while the claimed shelf life is of 2 years. You are required to submit complete stability data as per claimed shelf life.	The stability studies data for 12 months is attached. Firm requested to kindly grant us shelf life for 2 years (24 months)
iii.	Submit hard copy of original Legalized or apostille CoPP/ FSC and GMP and original Letter of authorization in office of Reg- Import & vet section of PE&R division.	The hard copies of apostilled CoPP, GMP, and letter of authorization is being submitted to DRAP office of reg Imp and vet section of PE&R division.

Decision:

- **Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.**
- **The shelf life of 12 months shall be allowed. However, firm may request for extension of shelf life after submission of stability studies.**
- **Firm will submit original legalized CoPP & letter of authorization.**

623.	**Name, address of Applicant / Importer**	**Alpha Evolution enterprises (Pvt.) Ltd** **Office No. 306, 4th floor, Magnum Arcade, E11/2, Islamabad Pakistan.**
	Details of Drug Sale License of importer	License No: DSL-768-ICT/2013 Address: Office No. 306, 4th floor, Magnum Arcade, E11/2, Islamabad Pakistan Address of godown: Shop # 02 & 06, Secon Hills, Northern Strip Markaz, e-11/2, Islamabad. Validity: 11-10-2023 Status: **Expired**
	Name and address of marketing authorization holder (abroad)	Joint Stock Company "FARMAK" Address: 63, Kyrylivska Street, Kyiv, 04080 Ukraine.
	Name, address of manufacturer(s)	Name: Joint Stock Company "FARMAK" Address: 74, Kyrylivska St., Kyiv, 04080, Ukraine; 4, Chornomorska St., Kyiv, 04080, Ukraine.
	Name of exporting country	Ukraine
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Original & Legalized** **Date of Legalization:** 28th November 2023 • **CoPP:** Firm has submitted original, apostilled CoPP certificate (No. CPP/UA/270/23) dated 12-12-2023 issued by State Service of Ukraine on Medicines and Drugs Control (SMDC). The CoPP specifies free sale status of the product in country of export along with its availability.

		• **GMP Certificate #** No. 084/2023/GMP**:** ✓ Issued on 19-10-2023 ✓ Validity: 02 years from date of issuance. ✓ Certificate confirms that drug manufacturer complies with the requirement of GMP.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization/Power of Attorney certificate from FARMAK FZ LLC, with its registered office at Dubai Science Park (DSP) Towers – North, Ninth floor, 909N, Dubai, UAE. License No: 98890 Date of Authorization: 29-08-2023 Details of entity authorized in Pakistan: Alpha Evolution Enterprises (Pvt.) Ltd. Head Office Address: Suite No. 306, 4th floor, Magnum Arcade, E/11-2, Islamabad.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. HU2-VG9-PM52 Dated: 27th December 2023
	Details of fee submitted	PKR 150000/-: 26th December 2023 Slip # 28339072
	The proposed proprietary name / brand name	Tomohexol 350mgI/ml solution for injection (100 ml vial)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100 ml vial contains: Iohexol……755mg/ml (755mg Iohexol equivalent to 350mg I)
	Pharmaceutical form of applied drug	Sterile Solution for injection
	Pharmacotherapeutic Group of (API)	Iodinated x-ray contrast media
	Reference to Finished product specifications	Ph. Eur. Specification
	Proposed Pack size	100 ml glass vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	OMNIPAQUE 350mgI/ml, MHRA approved formulation
	For generic drugs (me-too status)	OMNIPAQUE 350mgI/ml (Reg. # 8868)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch

		analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Name:** Zhejiang Starry Pharmaceutical Co., Ltd. **Address:** No.1 Starry Road of Xianju Modern Industrial Centralization Zone China-317 300 Xianju, Zhejiang Province
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 40º ±2 º C/75 ± 5% RH for 06 months. **Real time:** 25º ±2 º C/60 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Name:** OMNIPAQUE™ (other name ACCUPAQUE™) **Manufacturer**: GE Healthcare, Norway.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	100 mL in the glass bottle (Bormioli), 32 mm stopper (West), aluminium seal with a plastic cap (Datwyler)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches with manufacturing date 11/2022 **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 40ºC ±2ºC **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 09 months **Temperature:** 30ºC ±2ºC **Relative Humidity:** 75% ± 5%. Conclusions Based on the results of the long-term and accelerated stability studies of the drug product, no significant changes in critical quality attributes of the finished drug product were observed. The study results are provided in Section 3.2.P.8.3. The results of the stress testing of the developed product are provided in Section 3.2.P.5.3. Based on the obtained results, the following storage conditions of the drug product were set: The drug product does not require any special temperature storage conditions. Store containers in the original package to protect from light. A proposed shelf life of the drug product is 2 years.

Evaluation by PEC:

S#	Observations	Reply of the firm
i.	Certificate of pharmaceutical product on WHO format with pack sizes/volume per pack.	Submitted
ii.	The stability data submitted is for 09 months while the claimed shelf life is of 2 years. You are required to submit complete stability data as per claimed shelf life.	The stability studies data for 12 months is attached. Firm requested to kindly grant us shelf life for 2 years (24 months)
iii.	Submit hard copy of original Legalized or apostille CoPP/ FSC and GMP and original Letter of authorization in office of Reg- Import & vet section of PE&R division.	The hard copies of apostilled CoPP, GMP, and letter of authorization is being submitted to DRAP office of reg Imp and vet section of PE&R division.

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility. The shelf life shall be allowed as per the data of long term stability studies submitted before issuance of registration letter.

- **Firm will submit original legalized CoPP & letter of authorization.**

624.	**Name, address of Applicant / Importer**	**Alpha Evolution enterprises (Pvt.) Ltd** **Office No. 306, 4th floor, Magnum Arcade, E11/2, Islamabad Pakistan.**
	Details of Drug Sale License of importer	License No: DSL-768-ICT/2013 Address: Office No. 306, 4th floor, Magnum Arcade, E11/2, Islamabad Pakistan Address of godown: Shop # 02 & 06, Secon Hills, Northern Strip Markaz, e-11/2, Islamabad. Validity: 11-10-2023 Status: **Expired**
	Name and address of marketing authorization holder (abroad)	Joint Stock Company "FARMAK" Address: 63, Kyrylivska Street, Kyiv, 04080 Ukraine.
	Name, address of manufacturer(s)	Name: Joint Stock Company "FARMAK" Address: 74, Kyrylivska St., Kyiv, 04080, Ukraine; 4, Chornomorska St., Kyiv, 04080, Ukraine.
	Name of exporting country	Ukraine
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**<u>Original & Legalized</u>** **Date of Legalization:** 28th November 2023 • **CoPP:** Firm has submitted original, apostilled CoPP certificate (No. CPP/UA/270/23) dated 12-12-2023 issued by State Service of Ukraine on Medicines and Drugs Control (SMDC). The CoPP specifies free sale status of the product in country of export along with its availability. • **GMP Certificate #** No. 084/2023/GMP**:** ✓ Issued on 19-10-2023 ✓ Validity: 02 years from date of issuance. ✓ Certificate confirms that drug manufacturer complies with the requirement of GMP.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization/Power of Attorney certificate from FARMAK FZ LLC, with its registered office at Dubai Science Park (DSP) Towers – North, Ninth floor, 909N, Dubai, UAE. License No: 98890 Date of Authorization: 29-08-2023

		Details of entity authorized in Pakistan: Alpha Evolution Enterprises (Pvt.) Ltd. Head Office Address: Suite No. 306, 4th floor, Magnum Arcade, E/11-2, Islamabad.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. X33-5SH-8BUV Dated: 27th December 2023
	Details of fee submitted	PKR 150000/-: 26th December 2023 Slip # 404865272
	The proposed proprietary name / brand name	Tomohexol 350mgI/ml solution for injection (200 ml vial)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 200 ml vial contains: Iohexol……755mg/ml (755mg Iohexol equivalent to 350mg I)
	Pharmaceutical form of applied drug	Sterile Solution for injection
	Pharmacotherapeutic Group of (API)	Iodinated x-ray contrast media
	Reference to Finished product specifications	Ph. Eur. Specification
	Proposed Pack size	200 ml glass vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	OMNIPAQUE 350mgI/ml, MHRA approved formulation
	For generic drugs (me-too status)	OMNIPAQUE 350mgI/ml (Reg. # 8868)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Name:** Zhejiang Starry Pharmaceutical Co., Ltd. **Address:** No.1 Starry Road of Xianju Modern Industrial Centralization Zone China-317 300 Xianju, Zhejiang Province
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and

		stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 40º ±2 º C/75 ± 5% RH for 06 months. **Real time:** 25º ±2 º C/60 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Name:** OMNIPAQUE™ (other name ACCUPAQUE™) **Manufacturer**: GE Healthcare, Norway.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	200 mL in the glass bottle (Bormioli), 32 mm stopper (West), aluminium seal with a plastic cap (Datwyler)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches with manufacturing date 11/2022 **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 40ºC ±2ºC **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 09 months **Temperature:** 30ºC ±2ºC **Relative Humidity:** 75% ± 5%. Conclusions Based on the results of the long-term and accelerated stability studies of the drug product, no significant changes in critical quality attributes of the finished drug product were observed. The study results are provided in Section 3.2.P.8.3. The results of the stress testing of the developed product are provided in Section 3.2.P.5.3. Based on the obtained results, the following storage conditions of the drug product were set: The drug product does not require any special temperature storage conditions. Store containers in the original package to protect from light. A proposed shelf life of the drug product is 2 years.

Evaluation by PEC:

S#	Observations	Reply of the firm
i.	Certificate of pharmaceutical product on WHO format with pack sizes/volume per pack.	Submitted
ii.	The stability data submitted is for 09 months while the claimed shelf life is of 2 years. You are required to submit complete stability data as per claimed shelf life.	The stability studies data for 12 months is attached. Firm requested to grant shelf life for 2 years (24 months)
iii.	Submit hard copy of original Legalized or apostille CoPP/ FSC and GMP and original	The hard copies of apostilled CoPP, GMP, and letter of authorization is being submitted to DRAP office of reg Imp and vet section of PE&R division.

	Letter of authorization in office of Reg- Import & vet section of PE&R division.	

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility. The shelf life shall be allowed as per the data of long term stability studies submitted before issuance of registration letter.
Firm will submit original legalized CoPP & letter of authorization.

Item No. 04: Short Molecules priority application as per 178th meeting of the Authority:

625.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s NovaMed Pharmaceuticals (Pvt.) Ltd. (DML # 000590) 28-KM Ferozepur Road Lahore.**
	Name, address of Manufacturing site.	M/s NovaMed Pharmaceuticals (Pvt.) Ltd. (DML # 000590) 28-KM Ferozepur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate validity: 07-11-2026.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 232nd meeting held on 29th & 30th July 2013 approved the General Liquid Injection Vial (SVP).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. G64-NR5-PS2M dated 28-12-2023
	Details of fee submitted	PKR 30,000/-: Dated 28-12-2023 Slip # 92550451120
	The proposed proprietary name / brand name	Iohex Injection 50 ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 50 ml vial contains: Iohexol……755mg/ml (755mg Iohexol equivalent to 350mg I)
	Pharmaco-therapeutic Group of (API)	Sterile Solution for injection
	Pharmaceutical form of applied drug	Iodinated x-ray contrast media
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	50 ml glass vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation Omnipaque®
	For generic drugs (me-too status)	Omnipaque 350mg Injection / ml (Reg. # 8868)
	Name and address of API manufacturer.	Name: Zhejiang Hichi Pharmaceutical Corporation Limited Address: Changshun Road, Bingang Industrial Zone, Shamen Town, Yuhuan, Zhejiang, China. GMP validity : 13-01-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general

		properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Omnipaque 50ml **Manufactured by:** GE HealthCare Ireland. **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Zhejiang Hichi Pharmaceutical Corporation Limited Address: Changshun Road, Bingang Industrial Zone, Shamen Town, Yuhuan, Zhejiang, China.		
API Lot No.	C0042308001		
Description of Pack (Container closure system)	A clear glass vial containing a clear, colorless solution free from foreign particles, with a blue color flip off seal.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	RD/PR23- 278/T1/S1	RD/PR23- 278/T1/S2	RD/PR23- 278/T1/S3
Batch Size	100 vials	100 vials	100 vials
Manufacturing Date	09 -2023	09 -2023	09 -2023
Date of Initiation	28-09-2023	28-09-2023	28-09-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Clearance date: 22-09-2023 Quantity: 50 kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.3.4	• Please submit GMP certificate of your firm which should be valid till date.	Submitted
3.2.P.8	• Please justify that why analytical testing of free iodine has not been made part of your stability study?	Results are now submitted.
	• Please submit chromatograms for identification test of the retention times of the major peaks of the Sample solution correspond to those of the System suitability solution, as mention in the identification test of iohexol injection monograph of USP pharmacopeia.	Submitted
	• Please submit stability data for the last interval (06th month).	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

626.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s NovaMed Pharmaceuticals (Pvt.) Ltd. (DML # 000590) 28-KM Ferozepur Road Lahore.**
	Name, address of Manufacturing site.	M/s NovaMed Pharmaceuticals (Pvt.) Ltd. (DML # 000590) 28-KM Ferozepur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Certificate issued on the basis of inspection report dated 05th August 2021.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 232nd meeting held on 29th & 30th July 2013 approved the General Liquid Injection Vial (SVP).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. WPZ-ZNG-5LQL dated 28-12-2023
	Details of fee submitted	PKR 30,000/-: Dated 28-12-2023 Slip # 3322493583
	The proposed proprietary name /	Iohex Injection 100 ml

	brand name	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100 ml vial contains: Iohexol……755mg/ml (755mg Iohexol equivalent to 350mg I)
	Pharmaco-therapeutic Group of (API)	Sterile Solution for injection
	Pharmaceutical form of applied drug	Iodinated x-ray contrast media
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	100 ml glass vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation Omnipaque®
	For generic drugs (me-too status)	Omnipaque 350mg Injection / ml (Reg. # 8868)
	Name and address of API manufacturer.	Name: Zhejiang Hichi Pharmaceutical Corporation Limited Address: Changshun Road, Bingang Industrial Zone, Shamen Town, Yuhuan, Zhejiang, China. GMP validity : 13-01-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Omnipaque 100ml **Manufactured by:** GE HealthCare Ireland. **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API	Name: Zhejiang Hichi Pharmaceutical Corporation Limited	

	Address: Changshun Road, Bingang Industrial Zone, Shamen Town, Yuhuan, Zhejiang, China.		
API Lot No.	C0042308001		
Description of Pack (Container closure system)	A clear glass vial containing a clear, colorless solution free from foreign particles, with a blue color flip off seal.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	RD/PR23- 271/T1/S1	RD/PR23- 271/T1/S2	RD/PR23- 271/T1/S3
Batch Size	100 vials	100 vials	100 vials
Manufacturing Date	09 -2023	09 -2023	09 -2023
Date of Initiation	28-09-2023	28-09-2023	28-09-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Clearance date: 22-09-2023 Quantity: 50 kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.3.4	• Please submit GMP certificate of your firm which should be valid till date.	Submitted
3.2.P.8	• Please justify that why analytical testing of free iodine has not been made part of your stability study?	Results are now submitted.
	• Please submit chromatograms for identification test of the retention times of the major peaks of the Sample solution correspond to those of the System suitability solution, as mention in the identification test of iohexol injection monograph of USP pharmacopeia.	Submitted
	• Please submit stability data for the last interval (06th month).	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

627.	**Name, address of Applicant / Importer**	**M/s Ghazali Brothers** **Address: : 1st Floor, Azzainab Court, Campbell Street, Karachi Pakistan**
	Details of Drug Sale License of importer	**License No: 143** **Address: 19-SR-7 Combell Street AzzainabCourt 1st floor Karachi.** **Address of Godown: 1.S.NO.14 G/Floor Karimji & others Plot WO7/15 N.Napier .** 2.2D, 2nd FloorKarimji & others Plot No W07/15, N.Napier Karachi. **Validity: 26-10-2023** **Status: Expired** *Applied for renewal on time*
	Name and address of marketing authorization holder (abroad)	**Jiangsu Huayang Pharmaceuticals Co. Ltd.** **Address:** No.21, Changjiamg Road, Si Yung County, China.
	Name, address of manufacturer(s)	**Jiangsu Huayang Pharmaceuticals Co. Ltd.** **Address:** No.21, Changjiamg Road, Si Yung County, China.
	Name of exporting country	**CHINA.**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Date of Legalization:** not provided • CoPP: Firm has submitted CoPP certificate (No. 20230601002) dated 01-06-2023 issued by Anhui Drug Administration China. The CoPP specifies free sale status of the product in country of export along with its availability. CoPP Validity: 31-05-2028 • GMP: The firm has also submitted GMP certificate No. : JS20191088, Valid till invalidation of drug manufacturing license i.e. 31-12-2025
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from **Jiangsu Huayang Pharmaceuticals Co. Ltd. Address:** No.21, Changjiamg Road, Si Yung County, China. The letter certifies that "M/s Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street, Karachi Pakistan" is their exclusive agent to promote, register, commercialize and distribute company's (Calcium Gluconate Injection 1g/10ml) product in the territory of Pakistan. The letter was issued on 25-10-2019.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. WY6-33U-BQVN Dated: 08-03-2024
	Details of fee submitted	PKR 300,000/-: PKR 150000 dated 01-09-2022 (Slip # 169634016).

		+ PKR 150000 dated 01-03-2024 (Slip # 422119591)
	The proposed proprietary name / brand name	Calcium Gluconate Injection 1g/10ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 10 ml contains Calcium Gluconate …….. 980 mg
	Pharmaceutical form of applied drug	Sterile Liquid for injection
	Pharmacotherapeutic Group of (API)	Used in treatment of calcium deficiency
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	Type I clear Glass Ampoule
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA & MHRA approved formulation
	For generic drugs (me-too status)	Locally registered
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Name: Jiangxi Xinganjiang Pharmaceutical Co., Ltd Address: No.36, Yunzhang Road, Jizhou District, Ji'an City, Jiangxi Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API At accelerated 40 ± 5℃ / RH 75% for 06 months. Real time: 30 ± 5℃ / RH 65% for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has done pharmaceutical equivalence with generics of Chenxin Pharmaceutical China and submitted comparison of Pharmaceutical equivalence as testing parameters of BP specifications.

	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	10 ampoules are packed in one box
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches Accelerated Storage Conditions: Duration: 06 months Temperature: 40oC ±2oC Relative Humidity: 75% ± 5%. Long term Storage Conditions: Duration: 36 months Temperature: 30°C ±2oC Relative Humidity: 65% ± 5%.

Evaluation by PEC:

- Firm has to submit in hard copy, the legalized documents in original for CoPP, GMP Certificate of exporter & letter of authorization.

Section	Observations
3.2.P.1	• In the innovator product and other formulations approved in USFDA for FPP, each 10 ml of solution contains 940 or 950 mg of calcium gluconate, with an amount of calcium (equivalent to 94 mg or 95 mg of calcium gluconate) 4.5 mg of Calcium Saccharate, or other suitable calcium salts, for the purpose of stabilization. While in the formulation submitted by the manufacturer of applied drug product, each 10 ml of solution contains 980 mg of calcium gluconate. How will you justify the amount of calcium gluconate equivalent to 1g in the formulation and also mention the amount of total elemental calcium in the formulaiton? Please also provide reference of product with same formulation and composition approved in countries with stringent regulatory control declared by WHO.
3.2.P.2.7	• Please provide brand name of the medicinal product, formulation / composition and the address of manufacturer of the reference product used in Pharmaceutical equivalence studies.

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

628.	**Name, address of Applicant / Importer**	**M/s Ghazali Brothers** **Address: : 1st Floor, Azzainab Court, Campbell Street, Karachi Pakistan**
	Details of Drug Sale License of importer	**License No: 143** **Address: 19-SR-7 Combell Street AzzainabCourt 1st floor Karachi.** **Address of Godown: 1.S.NO.14 G/Floor Karimji & others Plot WO7/15 N.Napier .** 2.2D, 2nd FloorKarimji & others Plot No W07/15, N.Napier Karachi. **Validity: 26-10-2023** **Status: Expired** *Applied for renewal on time*
	Name and address of marketing authorization holder (abroad)	**Anhui Ocean Pharmaceutical Co., Ltd.** **Address:** No.1111, Longxing Road, Xiaobengbu Industrial Park, Huaishang District, Bengbu Anhui Province, **China.**
	Name, address of manufacturer(s)	**Anhui Ocean Pharmaceutical Co., Ltd.** **Address:** No.1918, Longhua Road, Bengbu, Anhui Province, **China.**
	Name of exporting country	**CHINA.**

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**<u>Photocopy</u>** **Date of Legalization:** not provided • **CoPP:** Firm has submitted CoPP certificate (No. 20230601002) dated 01-06-2023 issued by Anhui Drug Administration China. The CoPP specifies free sale status of the product in country of export along with its availability. CoPP Validity: 31-05-2028 • **GMP:** The firm has also submitted GMP compliance certificate No. : 20170363, Valid till invalidation of drug manufacturing license i.e. 31-12-2025
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from **Anhui Ocean Pharmaceutical Co., Ltd. Address:** No.1918, Longhua Road, Bengbu, Anhui Province, **China.** The letter certifies that "**M/s Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street, Karachi Pakistan**" is their exclusive agent to promote, register, commercialize and distribute company's *(Calcium Gluconate Injection 1g/10ml)* product in the territory of Pakistan. The letter was issued on 28-07-2021 valid for 05 years.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 7U3-9GJ-PAD7 Dated: 08-03-2024
	Details of fee submitted	PKR 300,000/-: PKR 150000 dated 28-12-2023 (Slip # 67337134054). **+** PKR 150000 dated 01-03-2024 (Slip # 67337134054)
	The proposed proprietary name / brand name	Calcium Gluconate Injection 1g/10ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 10 ml contains Calcium Gluconate …….. 1 G
	Pharmaceutical form of applied drug	Sterile Liquid for injection
	Pharmacotherapeutic Group of (API)	Used in treatment of calcium deficiency
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	Glass Ampoule
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA & MHRA approved formulation
	For generic drugs (me-too status)	Locally registered

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Name:** Shandong Xinhong Pharmaceutical Co. ,Ltd **Address:** Shanghe economic development zone, Jinan, Shandong, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 40 ± 5℃ / RH 75% for 06 months. **Real time:** 25 ± 5℃ / RH 60% for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has done pharmaceutical equivalence with generics of Chenxin Pharmaceutical China and submitted comparison of Pharmaceutical equivalence as testing parameters of BP specifications.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	10 ampoules are packed in one box
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 40ºC ±2ºC **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 36 months **Temperature:** 30ºC ±2ºC **Relative Humidity:** 75% ± 5%.

Evaluation by PEC:

- Firm has to submit in hard copy, the legalized documents in original for CoPP, GMP Certificate of exporter & letter of authorization.

Section	Observations
3.2.P.1	• In the innovator product and other formulations approved in USFDA with BP specifications for FPP, each 10 ml of solution contains 940 or 950 mg of calcium gluconate, with an amount of calcium (equivalent to 94 mg or 95 mg of calcium gluconate) in the form of Calcium Saccharate, or other suitable calcium salts, for the purpose of stabilization. While in the formulation submitted by the manufacturer of applied drug product, each 10 ml of solution contains 1g of calcium gluconate and also containing calcium hydroxide. How will you justify the amount of calcium is not exceeding 1g in the formulation? What is the role of sodium gluconate in the formulation? Please also provide reference of product with same formulation and composition approved in countries with stringent regulatory control declared by WHO.
3.2.P.2.7	• Please provide brand name of the medicinal product, formulation / composition and the address of manufacturer of the reference product used in Pharmaceutical equivalence studies.

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

Agenda of Assistant Director (PE&R) (Mr. Sarfraz)

Case no. 01 New Section

629.	Name, address of Applicant / Marketing Authorization Holder	M/s British Pharmaceuticals, 23 Km Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s British Pharmaceuticals, 23 Km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer
	GMP status of the firm	Additional sections granted for External/Topical preparations dated 27-12-2021
	Evidence of approval of manufacturing facility	External/Topical preparations, approval granted by DRAP (Central Licensing Board) vide letter No. F. 1-22/2010-Lic, dated: 27-12-2021
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ **Domestic sale**
	Dy. No. and date of submission	Dy.No 18079 dated 18-07-2023
	Details of fee submitted	Rs. 30,000/- dated 02-06-2023 Slip No. 896019857943
	The proposed proprietary name / brand name	**Povdine 10% Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 60ml contains: Povidone Iodine 10%w/v eq. to 1% w/v available Iodine
	Pharmacotherapeutic Group of (API)	Antiseptic ATC code: D08AG02
	Pharmaceutical form of applied drug	Topically liquid solution
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's (60ml, 90ml,100ml, 450ml) Bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Povidone-Iodine 10% w/w alcoholic tincture (MHRA)

	For generic drugs (me-too status)	Pyodine 10% Solution of M/s Brookes Pharma (Reg. 009528)
	Name and address of API manufacturer.	M/s Prachi Pharmaceuticals Pvt. Ltd. E-108, MIDC Tarapur, Boisar-401506 Dist. Thane Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence	Firm has submitted Pharmaceutical Equivalence of their product against the product Pyodine 10% (Batch No. 104J2) manufactured by M/s Brooks Pharma.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Prachi Pharmaceuticals Pvt. Ltd. E-108, MIDC Tarapur, Boisar-401506 Dist. Thane Maharashtra, India		
API Lot Number	PD 222311504		
Description of Pack (Container closure system)	Brownis colored solution filled in 60ml pet bottle with cap.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PV1	PV2	PV3
Batch Size	100Bottles	100Bottles	100Bottles

Manufacturing Date	09-2022	09-2022	09-2022
No. of Batches			

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP (Certificate No. 6104985) valid up to **01-08-2023** issued by Food & Drug Administration. Maharashtra State, India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of letter address to AD(PE&R)/PEC for evidence of Borrowing of API as Loan from M/s Pharma wise lab Lahore. The invoice of M/s Pharma wise lab Lahore for povine solution 10% is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable As per USP monograph method of assay is Titrimetric system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of evaluator:
GMP certificate of DS is not valid.

Decision: Approved. Firm shall submit valid DML/GMP certificate of Drug Substance manufacturer, before issuance of registration letter.

630.	Name, address of Applicant / Marketing Authorization Holder	M/s British Pharmaceuticals, 23 Km Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s British Pharmaceuticals, 23 Km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer
	GMP status of the firm	Additional sections granted for External/Topical preparations dated 27-12-2021
	Evidence of approval of manufacturing facility	External/Topical preparations, approval granted by DRAP (Central Licensing Board) vide letter No. F. 1-22/2010-Lic, dated: 27-12-2021
	Status of application	☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 18080 dated 18-07-2023
	Details of fee submitted	Rs. 30,000/- dated 02-06-2023 Slip No. 187032431745
	The proposed proprietary name / brand name	**Povdine 7.5% Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 60ml contains: Povidone Iodine 7.5%w/v eq. to 0.75% w/v available Iodine
	Pharmacotherapeutic Group of (API)	Antiseptic ATC code: D08AG02

	Pharmaceutical form of applied drug	Topically liquid solution
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's (60ml, 90ml,100ml, 450ml) Bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Povidone-Iodine 10% w/w alcoholic tincture (MHRA)
	For generic drugs (me-too status)	Pydon External Preparation of M/s Paradise Pharmaceuticals Lahore (Reg. 071551)
	Name and address of API manufacturer.	M/s Prachi Pharmaceuticals Pvt. Ltd. E-108, MIDC Tarapur, Boisar-401506 Dist. Thane Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence	Firm has submitted Pharmaceutical Equivalence of their product against the product Wondseptic 7.5% (Batch No. 2GLC1) manufactured by M/s Brooks Pharma.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Prachi Pharmaceuticals Pvt. Ltd. E-108, MIDC Tarapur, Boisar-401506 Dist. Thane Maharashtra, India
API Lot Number	PD 222311504
Description of Pack (Container closure system)	Brownis colored solution filled in 60ml pet bottle with cap.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PV1	PV2	PV3
Batch Size	100Bottles (60ml)	100Bottles (60ml)	100Bottles (60ml)
Manufacturing Date	09-2022	09-2022	09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP (Certificate No. 6104985) valid up to **01-08-2023** issued by Food & Drug Administration. Maharashtra State, India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of letter address to AD(PE&R)/PEC for evidence of Borrowing of API as Loan from M/s Pharma wise lab Lahore. The invoice of M/s Pharma wise lab Lahore for povine solution 7.5% is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable As per USP monograph method of assay is Titrimetric system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of evaluator:
GMP certificate of DS is not valid.

Decision: Approved. Firm shall submit valid DML/GMP certificate of Drug Substance manufacturer, before issuance of registration letter

631.	Name, address of Applicant / Marketing Authorization Holder	M/s British Pharmaceuticals, 23 Km Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s British Pharmaceuticals, 23 Km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	DML Renewal granted dated 12-01-2022
	Evidence of approval of manufacturing facility	Capsule (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 1-22/2010-Lic(vol-I), dated: 12-01-2022
	Status of application	☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ **Domestic sale**
	Dy. No. and date of submission	Dy.No 23762 dated 21-11-2023

	Details of fee submitted	Rs. 30,000/- dated 21-08-2023 Slip No. 9961795726
	The proposed proprietary name / brand name	**Bri-Eso 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Esomeprazole Coated pellets of magnesium trihydrate eq. to esomeprazole…20mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors ATC code: A02BC05
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1x10's, 2x7,s, 100,s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nexium 20mg capsule by Astrazeneca (USA)
	For generic drugs (me-too status)	Nexum 20mg Capsule by M/s Getz Pharma Pakistan Karachi (Reg. 033890)
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and comparative dissolution	Firm has submitted Pharmaceutical Equivalence and comparative dissolution with Nexum capsule 20mg (Getz Pharma)
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.		
API Lot Number	EMZ 046548		
Description of Pack (Container closure system)	Capsule with Purple colored cap and white body Alu-Alu Blister packed in bleached board unit carton UV Coated		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	B1	B2	B3
Batch Size	2000 Capsule	2000 Capsule	2000 Capsule
Manufacturing Date	10-2022	10-2022	10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP (Certificate No. 3-26/2019-Addl.Dir.(QA&LT-1)-56 valid up to 13-06-2024 issued by QA&LT, DRAP Islamabad
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of locally purchased from M/s Vision Pharmaceuticals dated 13-10-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

632.	Name, address of Applicant / Marketing Authorization Holder	M/s British Pharmaceuticals, 23 Km Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s British Pharmaceuticals, 23 Km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	DML Renewal granted dated 12-01-2022

	Evidence of approval of manufacturing facility	Capsule (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 1-22/2010-Lic(vol-I), dated: 12-01-2022
	Status of application	☐ **New Drug Product (NDP)** ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ **Domestic sale** ☐ Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy.No 23763 dated 21-11-2023
	Details of fee submitted	Rs. 30,000/- dated 21-08-2023 Slip No. 003280258
	The proposed proprietary name / brand name	**Bri-Eso 40mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Esomeprazole Coated pellets of magnesium trihydrate eq. to esomeprazole…40mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors ATC code: A02BC05
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1x10's, 2x7,s, 100,s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nexium 40mg capsule by Astrazeneca (USA)
	For generic drugs (me-too status)	Nexum 40mg Capsule by M/s Getz Pharma Pakistan Karachi (Reg. 033891)
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	The firm has submitted detail of manufacturer, description of

		manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and comparative dissolution	Firm has submitted Pharmaceutical Equivalence and comparative dissolution with Nexum capsule 40mg (Getz Pharma)
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.		
API Lot Number	EMZ 046535		
Description of Pack (Container closure system)	Capsule with Purple colored cap and white body Alu-Alu Blister packed in bleached board unit carton UV Coated		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	B1	B2	B3
Batch Size	2000 Capsule	2000 Capsule	2000 Capsule
Manufacturing Date	10-2022	10-2022	10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP (Certificate No. 3-26/2019-Addl.Dir.(QA&LT-1)-56 valid up to 13-06-2024 issued by QA&LT, DRAP Islamabad
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of locally purchased from M/s Vision Pharmaceuticals dated 30-09-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

633.	Name, address of Applicant / Marketing Authorization Holder	M/s British Pharmaceuticals, 23 Km Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s British Pharmaceuticals, 23 Km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	DML Renewal granted dated 12-01-2022
	Evidence of approval of manufacturing facility	Tablet (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 1-22/2010-Lic(vol-I), dated: 12-01-2022
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ **Domestic sale** ☐ Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy.No 19399 dated 04-08-2023
	Details of fee submitted	Rs. 30,000/- dated 19-07-2023 Slip No. 8748740324
	The proposed proprietary name / brand name	**Brithro 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Azithromycin Dihydrate eq. to Azithromycin 250mg
	Pharmacotherapeutic Group of (API)	Antibiotic ATC code: J01FA10
	Pharmaceutical form of applied drug	film coated tablet
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	3’s, 6’s, 10’s, 14’s, 20’s, 100’s, 200’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**ZITHROMAX Tablet** by Pfizer (USA)
	For generic drugs (me-too status)	Zetro 250mg tablet by M/s Getz Pharma Pakistan Karachi (Reg. 045375)
	Name and address of API manufacturer.	M/s Citi pharma pvt. Ltd. 3km head balloki road, phool nagar, Kasur-55050 DML No. 000429(Semi Basic)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for

		impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and comparative dissolution	Firm has submitted Pharmaceutical Equivalence and comparative dissolution with Azitma 250 tablet (Sami Pharma)
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Citi pharma pvt. Ltd. 3km head balloki road, phool nagar, Kasur-55050 DML No. 000429(Semi Basic)		
API Lot Number	AZM 2207001		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	B1	B2	B3
Batch Size	500 Tablets	500 Tablets	500 Tablets
Manufacturing Date	08-2022	08-2022	08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP (Certificate No. 31/2023-DRAP(AD-54697225495 Dated 09-03-2023 inspection dated 03-03-2023 issued by DRAP Lahore
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of locally purchased from M/s Citi pharma dated 17-10-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

634.	Name, address of Applicant / Marketing Authorization Holder	M/s British Pharmaceuticals, 23 Km Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s British Pharmaceuticals, 23 Km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	DML Renewal granted dated 12-01-2022
	Evidence of approval of manufacturing facility	Tablet (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 1-22/2010-Lic(vol-I), dated: 12-01-2022
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ **Domestic sale** ☐ Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy.No 19400 dated 04-08-2023
	Details of fee submitted	Rs. 30,000/- dated 19-07-2023 Slip No. 3792874871
	The proposed proprietary name / brand name	**Brithro 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Azithromycin Dihydrate eq. to Azithromycin 500mg
	Pharmacotherapeutic Group of (API)	Antibiotic ATC code: J01FA10
	Pharmaceutical form of applied drug	film coated tablet
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	3’s, 6’s, 10’s, 14’s, 20’s, 100’s, 200’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**ZITHROMAX Tablet** by Pfizer (USA)
	For generic drugs (me-too status)	Zetro 500mg tablet by M/s Getz Pharma Pakistan Karachi (Reg. 053120)
	Name and address of API manufacturer.	M/s Citi pharma pvt. Ltd. 3km head balloki road, phool nagar, Kasur-55050 DML No. 000429(Semi Basic)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.

		Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and comparative dissolution	Firm has submitted Pharmaceutical Equivalence and comparative dissolution with Zetro tablet 500mg (Getz Pharma)
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Citi pharma pvt. Ltd. 3km head balloki road, phool nagar, Kasur-55050 DML No. 000429(Semi Basic)		
API Lot Number	AZM 2207001		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	B1	B2	B3
Batch Size	500 Tablets	500 Tablets	500 Tablets
Manufacturing Date	08-2022	08-2022	08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP (Certificate No. 31/2023-DRAP(AD-54697225495 Dated 09-03-2023 inspection dated 03-03-2023 issued by DRAP Lahore
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of locally purchased from M/s Citi pharma dated 17-10-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

635.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Name, address of Manufacturing site.	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Status of the applicant	Manufacturer
	GMP status of the firm	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Eye/Ear Drops(General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Eye/Ear Drops(General) section.
	Status of application	Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic and Export sales
	Dy. No. and date of submission	January 12th, 2024, 7:34 am
	Details of fee submitted	PKR 30,000/- Dated 19-12-2023 Challan No. 8734923126
	The proposed proprietary name / brand name	Alcipro Eye Drop 0.3%
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ciprofloxacin Hydrochloride as Ciprofloxacin 3mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	Eye Drops Solution, A clear and Colourless to pale yellow Solution
	Reference to Finished product specifications	USP
	Proposed Pack size	5 ml Drop-Tainer LDPE bottle and plug with a polystyrene or polypropylene cap.

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**CILOXAN** (USFDA Approved)
	For generic drugs (me-too status)	Rocip Eye Drop 0.3% of Remington Pharmaceutical Industries (Reg.No. 015693)
	Name and address of API manufacturer.	Zhejiang Xinhua Pharmaceutical Co., Ltd Zhejiang Provincial chemical and medical materials base linhai zone, linhai, Zhejiang, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Firm has submitted pharmaceutical equivalence of their product against Rocip Eye Drop 0.3% of Remington Pharmaceutical Industries.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Zhejiang Xinhua Pharmaceutical Co., Ltd Zhejiang Provincial chemical and medical materials base linhai zone, linhai, Zhejiang, China
API Lot No.	ZCFX21-015
Description of Pack (Container closure system)	Packed in 5 ml Drop-Tainer LDPE bottle and plug with a polystyrene or polypropylene cap.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-TB01ED	CP-TB02ED	CP-TB03ED
Batch Size	800 Bottles	800 Bottles	800 Bottles
Manufacturing Date	05-2023	05-2023	05-2023
Date of Initiation	17-05-2023	17-05-2023	17-05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice DC No. 00036/0922 dated 20-09-2022 for API Loan received from M/s Newton Health Care Pvt. Ltd Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

i. Submit DRAP Clearance from M/s Newton Health Care Pvt. Ltd Karachi for requisite API.

ii. Submit copy of GMP certificate from API manufacturer abroad.

Firm Reply:

Dear Sir

M/S Zenith Chemical Industries (Pvt) Ltd, is local Lahore based manufacturer. There is no any need of clearance required from DRAP, while we are enclosing the GMP Certificate of M/S Zenith Chemical Industries (Pvt) Ltd attached.

Remarks of Evaluator:

Manufacturer of Drug Substance as per Form-5F and firm reply are as under:

Manufacturer of DS as per Form-5F	**As per query reply Manufacturer of DS**
Zhejiang Xinhua Pharmaceutical Co., Ltd Zhejiang Provincial chemical and medical materials base linhai zone, linhai, Zhejiang, China	M/S Zenith Chemical Industries (Pvt) Ltd, Lahore Pakistan

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

636.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Name, address of Manufacturing site.	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro,

		Pakistan
	Status of the applicant	Manufacturer
	GMP status of the firm	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Liquid Ampoule(General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Liquid Ampoule(General) section.
	Status of application	Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic and Export sales
	Dy. No. and date of submission	January 8th, 2024, 1:20 pm
	Details of fee submitted	PKR 30,000/- Dated 27-12-2023 Challan No. 95030131551
	The proposed proprietary name / brand name	Sterile Water for Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml ampoule contains: Sterile Water for Injection .....5 ml
	Pharmacotherapeutic Group of (API)	
	Pharmaceutical form of applied drug	Injection
	Reference to Finished product specifications	BP
	Proposed Pack size	5 mlx100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Water for Injections BP (MHRA Approved)
	For generic drugs (me-too status)	Sterile water for injection of M/s Gsk (Reg.No. 014865)
	Name and address of API manufacturer.	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures, conductivity, and its validation, batch analysis and justification of specification, container closure system and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, container closure system.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Not Applicable
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of

		drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Firm has submitted pharmaceutical equivalence of their product against Sterile water for injection of M/s Wuhan Grand Pharma Co, Ltd. China.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan		
API Lot No.	WFI-TB-001,2,3		
Description of Pack (Container closure system)	5ml Clear glass ampoules		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	WFI-TB-001	WFI-TB-002	WFI-TB-003
Batch Size	3000 Ampoules	3000 Ampoules	3000 Ampoules
Manufacturing Date	05-2023	05-2023	05-2023
Date of Initiation	17-05-2023	17-05-2023	17-05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Liquid Ampoule(General) section.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Applicable
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Applicable
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
637.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Name, address of Manufacturing site.	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Status of the applicant	Manufacturer
	GMP status of the firm	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Liquid Injectable Vial SVP(General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Liquid Injectable Vial SVP(General) section.
	Status of application	Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic and Export sales
	Dy. No. and date of submission	January 1st, 2024, 6:05 pm
	Details of fee submitted	PKR 30,000/- Dated 02-12-2023 Challan No. 728155159519
	The proposed proprietary name / brand name	**Alcipro Infusion 200mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Ciprofloxacin Lactate as Ciprofloxacin 200mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	Intravenous infusion
	Reference to Finished product specifications	USP
	Proposed Pack size	100ml glass vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciprofloxacin 2 mg/ml Solution for Infusion (MHRA Approved)
	For generic drugs (me-too status)	Quinoflox Infusion (Reg. 048423) of M/s Bosch Pharmaceuticals Pvt. Limited.
	Name and address of API manufacturer.	Zhejiang Guobang Pharmaceutical Co., Ltd (abbreviated as ZJGB) No. 6, weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejinag 312369, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing

		process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Firm has submitted pharmaceutical equivalence of their product against Quinoflox Infusion (Reg. 048423) of M/s Bosch Pharmaceuticals Pvt. Limited.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Guobang Pharmaceutical Co., Ltd (abbreviated as ZJGB) No. 6, weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejinag 312369, China		
API Lot No.	DK21-2111224		
Description of Pack (Container closure system)	100ml glass vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-TB 001	CP-TB 002	CP-TB 003
Batch Size	300 Bottles	300 Bottles	300 Bottles
Manufacturing Date	05-2023	05-2023	05-2023
Date of Initiation	16-05-2023	16-05-2023	16-05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has stated that API as loan received from Bosch Pharmaceutical Pvt. Ltd.

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

Remarks of Evaluator:

i. In Form 5-F, you mentioned that the API was obtained as a loan from Bosch Pharmaceutical Pvt. Ltd. However, the attached receipt is from M/s Newton Health Care Pvt. Ltd. in Karachi. Provide clarification with supporting documents, and include DRAP clearance for the API importer.

ii. Submit copy of GMP certificate from API manufacturer abroad.

Firm Reply:

This is to inform you that in the CTD Dossier Alcipro Infusion 200mg/100ml, we received API as loan from Indus Pharmaceuticals (Pvt) Ltd. It is an extra page added during the scanning of dossier. We are enclosing the supporting documents of API attached.

As per Document (GMP copy) manufacturer of API is as under:

M/s Shangyu Jingxin Pharmaceutical Co., Ltd. No. 31 Weisan Road, Hangzhou Bay, Shangyu, Shangyu Economic and Technological Development Area, China.

Remarks of Evaluator:

Manufacturer of Drug Substance as per Form-5F and firm reply are as under:

Manufacturer of DS as per Form-5F	**As per query reply Manufacturer of DS**
Zhejiang Guobang Pharmaceutical Co., Ltd (abbreviated as ZJGB) No. 6, weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejinag 312369, China	M/s Shangyu Jingxin Pharmaceutical Co., Ltd. No. 31 Weisan Road, Hangzhou Bay, Shangyu, Shangyu Economic and Technological Development Area, China.

Decision: The board deferred the case for the submission of short comings communicated.

638.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Name, address of Manufacturing site.	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Status of the applicant	Manufacturer
	GMP status of the firm	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Liquid Injectable vial SVP(General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Liquid Injectable vial SVP(General) section.
	Status of application	Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic and Export sales
	Dy. No. and date of submission	December 18th, 2023, 2:46 pm
	Details of fee submitted	PKR 30,000/- Dated 02-12-2023 Challan No. 5389981692
	The proposed proprietary name / brand	Levoful Infusion 500mg

	name	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100 ml vial contains Levofloxacin as Hemihydrate.....500 mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	Infusion
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	100ml vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levofloxacin 5mg/ml solution for infusion (MHRA Approved)
	For generic drugs (me-too status)	Leflox Infusion of M/s Getz Pharma Pvt. Ltd. (Reg.No. 024664)
	Name and address of API manufacturer.	Zhejiang East-Asia Pharmaceutical Co., Ltd. Economic Development Zone of Sanmen Country, Zhejiang 317100,P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Firm has submitted pharmaceutical equivalence of their product against Leflox Infusion of M/s Getz Pharma Pvt. Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	Zhejiang East-Asia Pharmaceutical Co., Ltd. Economic Development Zone of Sanmen Country, Zhejiang 317100,P.R. China		
API Lot No.	DK21-2111224		
Description of Pack (Container closure system)	100ml glass vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LF-TB-001	LF-TB-002	LF-TB-003
Batch Size	30 L	30 L	30 L
Manufacturing Date	05-2023	05-2023	05-2023
Date of Initiation	02-06-2023	02-06-2023	02-06-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has inform that API received as loan from M/s Newton Health Care Pvt. Ltd. and submit DRAP clearance dated 07-07-2022 of said firm.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Analysis performed on HPLC system which is not CFR 21 compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Submit a copy of the GMP certificate from the API manufacturer abroad.

Why is product testing not performed using HPLC software 21CFR?

Firm Reply:

This to inform you that in CTD Dossier Levoful Infusion 500mg/100ml the statement against the point Compliance record of HPLC Software 21CFR & audit trail reports on product testing, the statement given The analysis performed was on using HPLC Software System which is not CFR 21 compliant. It is a typographical error made by us so for this mistake we apologize and request you to omit the word not. We are performing analysis on CFR 21 compliant system.

Remarks of Evaluator:

Manufacturer of Drug Substance as per Form-5F and firm reply are as under:

Manufacturer of DS as per Form-5F	**As per query reply Manufacturer of DS**

	Zhejiang East-Asia Pharmaceutical Co., Ltd. Economic Development Zone of Sanmen Country, Zhejiang 317100,P.R. China	Zhejiang East-Asia Pharmaceutical Co., Ltd. Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China Copy of GMP shows validity till 15-08-2021
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings		
639.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Name, address of Manufacturing site.	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Status of the applicant	Manufacturer
	GMP status of the firm	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Liquid Ampoule(General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Liquid Ampoule(General) section.
	Status of application	Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic and Export sales
	Dy. No. and date of submission	January 29th, 2024, 10:39 am
	Details of fee submitted	PKR 30,000/- Dated Dec 19, 2023 4:33 PM Challan No. 8628547720
	The proposed proprietary name / brand name	Alvit Injection 1000mcg/ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contain: Vitamin B12 .....1000mcg
	Pharmacotherapeutic Group of (API)	Vitamin ATC Code B03BA01
	Pharmaceutical form of applied drug	IV/IM Injection
	Reference to Finished product specifications	USP
	Proposed Pack size	Amber colour glass ampoule 1mlx100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	(PDMA Japan approved)
	For generic drugs (me-too status)	Vitamin B12 Injection of M/s Amrose Pharmaceutical (Reg.No. 026880)
	Name and address of API manufacturer.	M/s Yuxing Bio-Technology (Group) Co., Ltd. Xicheng, Distric, Ningjin county, Xing Tai City, Hebei Province, China COA of DS from this. As per Module-2 Hebei Huarong Pharmaceutical Co., Ltd. East Road, North Circle, Shijiazhuang, Hebei, China Secondary ref. standard use from this. API Manufacturer as per Module 3 Sichuan Province Yuxin Pharmaceutical Co., Ltd No. 51, West Section of Changjiang Road, Shifang Economic Development Zone (Southern District), Sichuan.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Firm has submitted pharmaceutical equivalence of their product against Cyanocobalmin Injection of M/a Amaan Pharma Lahore
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Hebei Huarong Pharmaceutical Co., Ltd. East Road, North Circle, Shijiazhuang, Hebei, China Secondary ref. standard use from this.		
API Lot No.	C210806F		
Description of Pack (Container closure system)	Amber colour glass ampoule 1ml		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	VT-TB-001	VT-TB-002	VT-TB-003
Batch Size	3000 Ampoule	3000 Ampoule	3000 Ampoule
Manufacturing Date	05-2023	05-2023	05-2023
Date of Initiation	15-05-2023	15-05-2023	15-05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	API received as loan from M/s Ahsons Drug Company Tando Adam firm submitted copy of Drud Import License No. K-1490452716974 API manufacturer M/s M/s Yuxing Bio-Technology (Group) Co., Ltd. Xicheng, Distric, Ningjin county, Xing Tai City, Hebei Province, China
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API received as loan from M/s Ahsons Drug Company Tando Adam firm submitted copy of Drud Import License No. K-1490452716974 API manufacturer M/s M/s Yuxing Bio-Technology (Group) Co., Ltd. Xicheng, Distric, Ningjin county, Xing Tai City, Hebei Province, China
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	As per USP Monograph analysis was performed using UV Spectrophotometer.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Shortcomings/Clarification	**Firm response**
Module 1 states that the API manufacturer is M/s Yuxing Bio-Technology (Group) Co., Ltd., located in Xicheng District, Ningjin County, Xing Tai City, Hebei Province, China. The Certificate of Analysis (COA) for the Drug Substance (DS) is obtained from this manufacturer. According to Module 2, the API manufacturer is M/s Hebei Huarong Pharmaceutical Co., Ltd., situated on East Road, North Circle, Shijiazhuang, Hebei, China, and the secondary reference standard is sourced from this manufacturer. In Module 3, the API manufacturer is M/s Sichuan Province Yuxin Pharmaceutical Co., Ltd., located at No. 51, West Section of Changjiang Road, Shifang Economic Development Zone (Southern District), Sichuan. You are advised to clarification with supporting documents regarding the API manufacturer used for product development.	This is to inform you that the API Manufacturer of Vitamin B12 (Cyanocobalamin) is M/s. Yuxing Biotechnology (Group) Co. Ltd. The certificate of analysis COA for the Drug Substance is also same as M/s. Yuxing Biotechnology (Group) Co. Ltd. The drug product manufactured from same manufacturer M/s. Yuxing Biotechnology (Group) Co. Ltd. We are enclosing the supporting documents also.
The stability data for batch no. VT-TB-001 indicates an initiation date of 15-05-2023, but within the same dataset, the initiation date is mentioned as 12-05-2023. Similarly, for Batch no. VT-TB-002, the initiation date is stated as 15-05-2023, while in the table, it is documented as 13-05-2023. Please provide clarification on this discrepancy.	The stability data for batch No. VT-TB-001 indicates an initiation date of 15/05/2023 while the 12/05/2023 is the analysis date of batch No. VT-TB-001, Similarly batch No. VT-TB-002 indicates an initiation date of 15/05/2023 while the 13/05/2023 is the analysis date of batch No. VT-TB-002.

Decision. The board deferred for submission of following:

• **Details of drug substance manufacturer along with evidence of procurement attested by AD I&E DRAP.** • **Clarification regarding dates of manufacturing and initial analysis of batch release of stability trial batches along with relevant manufacturing and analytical record.**		
640.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Name, address of Manufacturing site.	**M/s** Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshoro, Pakistan
	Status of the applicant	Manufacturer
	GMP status of the firm	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Eye/Ear Drops(General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Issuance of New DML No. 000973 (Formulation) dated 18-10-2023 specifying Eye/Ear Drops(General) section.
	Status of application	Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic and Export sales
	Dy. No. and date of submission	January 18th, 2024, 2:21 pm
	Details of fee submitted	PKR 30,000/- Dated Dec 19, 2023 4:32 PM Challan No. 108672030604
	The proposed proprietary name / brand name	Almox Eye Drop 0.5%
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Moxifloxacin Hydrochloride as Moxifloxacin 5mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	Eye Drops, Solution
	Reference to Finished product specifications	USP
	Proposed Pack size	5 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Vigamox** (USFDA Approved)
	For generic drugs (me-too status)	Moxigan 0.5% Sterile Ophthalmic Solution Of M/s Barrett Hodgson Pakistan (Pvt) Ltd.,Karachi (Reg.No. 042111)
	Name and address of API manufacturer.	Module 1 M/s Shankus Pharma Pvt. Ltd Plot No. 9,10,11, Milan Industrial Estate, Vadsar Road, Santej, Tal; Kalol, Dist. Gandhinagar, Gujarat, India M-2 API Manufacturer: M/s Orex Pharma Pvt. Ltd. C/O Cureworth Drugs and intermedia tes pvt. Ltd. India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and

		controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Firm has submitted pharmaceutical equivalence of their product against Moxigan 0.5% Sterile Ophthalmic Solution of M/s Barrett Hodgson Pakistan (Pvt) Ltd.,Karachi (Reg.No. 042111)
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API			
API Lot No.	Mox 21103		
Description of Pack (Container closure system)	Pale yellow to greenish colour clear solution filled in 5ml drop trainer LDPE Bottle plug with a polystyrene or polypropylene cap.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MOX-TB01ED	MOX-TB02ED	MOX-TB03ED
Batch Size	800 Bottles	800 Bottles	800 Bottles
Manufacturing Date	05-2023	05-2023	05-2023
Date of Initiation	21-05-2023	21-05-2023	21-05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has inform that API Loan received from M/s Newton Health Care Pvt. Ltd Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Shortcomings/Clarification	**Firm response**
Submit DRAP Clearance from M/s Newton Health Care Pvt. Ltd Karachi for requisite API.	Not submitted
Submit copy of valid GMP certificate from API manufacturer abroad.	Not submitted
Submit DS data from API used for DP	Not submitted

Remarks of Evaluator:
Manufacturer of Drug Substance as per Form-5F and firm reply are as under:

Manufacturer of DS as per Form-5F	**As per query reply Manufacturer of DS**
Module 1 M/s Shankus Pharma Pvt. Ltd Plot No. 9,10,11, Milan Industrial Estate, Vadsar Road, Santej, Tal; Kalol, Dist. Gandhinagar, Gujarat, India Module-2 API Manufacturer: M/s Orex Pharma Pvt. Ltd. C/O Cureworth Drugs and intermedia tes pvt. Ltd. India	M/S Zenith Chemical Industries (Pvt) Ltd, Lahore Pakistan

Deferred for submission of following:

- **Details of drug substance manufacturer along with evidence of procurement attested by AD I&E DRAP.**
- **Copy of valid GMP certificate from API manufacturer abroad.**

641.	Name, address of Applicant / Marketing Authorization Holder	M/s Biogen Life Scieces, 8-KM, Chak Beli Road, Rawat,
	Name, address of Manufacturing site.	M/s Biogen Life Scieces, 8-KM, Chak Beli Road, Rawat,
	Status of the applicant	Manufacturer
	GMP status of the firm	DML No. 000911granted dated 13-02-2020
	Evidence of approval of manufacturing facility	Capsule (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 1-2/2019-Lic, dated: 14-02-2020
	Status of application	☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic and Export sales
	Dy. No. and date of submission	January 13th, 2024, 10:50 am

	Details of fee submitted	Rs. 30,000/- dated Jan 12, 2024 Slip No. 7647112917 Differencial fee Rs. 270,000/- dated Jan 19, 2024 slip no. 287191947604
	The proposed proprietary name / brand name	Dutaride-T Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) …… 0.5 mg Tamsulosin hydrochloride (as modified release pellets) …….0.4 mg
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists ATC Code G04CA52
	Pharmaceutical form of applied drug	Oral Capsule
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dutasteride/Tamsulosin hydrochloride 0.5 mg / 0.4 mg hard capsules (MHRA)
	For generic drugs (me-too status)	Maxflow-D Capsule by M/s CCL Pharmaceutical (Reg. 091571)
	Name and address of API manufacturer	Tamsulosin Hydrochloride by M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad. Dutasteride by M/s Softgel Health Care (Pvt) Ltd Survey No: 20/1, Vendalur Kelambakkam road, Pudupakkam Village, Kancheepuram District
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months for Tamsulosin and 48 months for dutasteride
	Module-III Drug Product:	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of

		drug product.
	Pharmaceutical Equivalence and comparative dissolution	Firm has submitted Pharmaceutical Equivalence and comparative dissolution with Doudart Capsule of Gsk.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Tamsulosin Hydrochloride by M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad. Dutasteride by M/s Softgel Health Care (Pvt) Ltd Survey No: 20/1, Vendalur Kelambakkam road, Pudupakkam Village, Kancheepuram District		
API Lot Number			
Description of Pack (Container closure system)	Brick red soft gel capsules containing clear colorless to pale yellow solution & off white spherical pellets filled in blue/white hard gelatin capsules		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 Capsules	1000 Capsules	1000 Capsules
Manufacturing Date	11-2022	11-2022	11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP (Certificate No. 3-26/2019-Addl.Dir.(QA&LT-1)-56 valid up to 13-06-2024 issued by QA&LT, DRAP Islamabad to M/s Vision Pharmaceuticals Islamabad Firm submitted Eudra GMDP certificate of Dutasteride API manufacturer online access dated 16-02-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our HPLC system is not 21 CFR compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of evaluator:

Shortcomings/Deficiencies	**Firm reply**
Valid GMP certificate from both API manufacturers	Submitted

Copy of agreement between manufacturer and API supplier.	We have used Tamsulosin pellets and Dutasteride soft gelatin capsule in our product. Both of these ingredients have been procured from the manufacturers as semi-finished ingredients. Since both the suppliers are providing these substances to other manufacturers also so an exclusive agreement is not available.
API import invoices for product development.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

642.	Name, address of Applicant / Marketing Authorization Holder	M/s Biogen Life Scieces, 8-KM, Chak Beli Road, Rawat,
	Name, address of Manufacturing site.	M/s Biogen Life Scieces, 8-KM, Chak Beli Road, Rawat,
	Status of the applicant	Manufacturer
	GMP status of the firm	DML No. 000911granted dated 13-02-2020
	Evidence of approval of manufacturing facility	Ampoule section (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 1-2/2019-Lic, dated: 14-02-2020
	Status of application	☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic and Export sales
	Dy. No. and date of submission	December 27th, 2023, 9:32 am
	Details of fee submitted	Rs. 30,000/- dated Dec 19, 2023 Slip No. 430579121639
	The proposed proprietary name / brand name	Calcigen 1mcg/ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml ampoule contains:- Calcitriol……..1mcg
	Pharmacotherapeutic Group of (API)	Vitamin D3 WHO ATC Code A11CC04
	Pharmaceutical form of applied drug	Injection
	Reference to Finished product specifications	USP
	Proposed Pack size	1ml x5's, 1ml x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CALCIJEX® (calcitriol injection) 1 mcg/mL Approved by FDA
	For generic drugs (me-too status)	Rotex Pharamceuticals (Reg. No. 107285)
	Name and address of API manufacturer	CARBOGEN AMCIS B.V. Nieuweweg 2a 3901 BE Veenendaal The Netherlands
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its

		validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm has submitted EDQM Certificate access from online dated 27-02-2024. Certificates Results (edqm.eu)
	Module-III Drug Product:	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and comparative dissolution	Firm has submitted Pharmaceutical Equivalence with innovator product
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA			
API Lot Number	042951		
Description of Pack (Container closure system)	Clear colorless solution filled in transparent glass USP type-1 Ampoule filled with solution for injection, further packed in bleach board pack containing 5 ampoules with Alu/PVC blister and insert		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CL050	CL051	CL052
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	07-2023	07-2023	07-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Online access from official data base of Eudra GmDPDated 27-02-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of DRAP clearance submitted dated 11-07-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Approved.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
643.	Name, address of Applicant / Marketing Authorization Holder	M/s Biogen Life Scieces, 8-KM, Chak Beli Road, Rawat,
	Name, address of Manufacturing site.	M/s Biogen Life Scieces, 8-KM, Chak Beli Road, Rawat,
	Status of the applicant	Manufacturer
	GMP status of the firm	DML No. 000911granted dated 13-02-2020
	Evidence of approval of manufacturing facility	Tablet section (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 1-2/2019-Lic, dated: 14-02-2020
	Status of application	☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic and Export sales
	Dy. No. and date of submission	December 20th, 2023, 2:10 pm
	Details of fee submitted	Rs. 30,000/- dated Dec 19, 2023 Slip No. 0367163333
	The proposed proprietary name / brand name	Mecogen 0.5mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sugar coating tablet contains: Mecobalamin ……0.5mg
	Pharmacotherapeutic Group of (API)	Vitamin B12 ATC Code **B03BA05**
	Pharmaceutical form of applied drug	Tablet
	Reference to Finished product specifications	JP
	Proposed Pack size	1x10's , 1x30's, 100
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Mecobalamin 500mcg sugar coated tablet PMDA Japan Approved
	For generic drugs (me-too status)	Mecomed 500mcg Manufactured By: Global Pharma Reg. No. 041670)
	Name and address of API manufacturer	Mahima Life Sciences Pvt. Ltd. Address: 1C, 1ST Floor, Big Jo's Tower, Netaji Subhash Place, Pitampura, New Delhi, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm has submitted stability studies at 30˚C ± 2˚C / 65% ± 5%RH for 48 months and accelerated at 40˚C ± 2˚C / 75% ± 5%RH for 6 months.
	Module-III Drug Product:	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical

		procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and comparative dissolution	Firm has submitted Pharmaceutical Equivalence and CDP with reference product of M/s Eiasi Co. Ltd JP Limited
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA

Description of Pack (Container closure system)	Alu-PVC Blister packed in card board unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MC 011	MC012	MC013
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	07-2023	07-2023	07-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate from manufacturer abroad issued by State Drug Controller Haryana Food and Drug Administration Haryana
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of DRAP clearance submitted dated 23-06-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC System is not 21 CFR Compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

644.	Name, address of Applicant / Marketing Authorization Holder	M/s Safina Pharmaceutical (Pvt) Ltd, 17 km. Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s Safina Pharmaceutical (Pvt) Ltd, 17 km. Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer

	GMP status of the firm	New DML dated 09-06-2021
	Evidence of approval of manufacturing facility	Capsule (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 1-43/2006-Lic(vol-I), dated: 10-06-2021
	Status of application	☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ **Domestic sale**
	Dy. No. and date of submission	January 15th, 2024, 4:49 pm
	Details of fee submitted	Rs. 30,000/- **Posting Date** Jan 15, 2024 1:03 PM Slip No. 85758366
	The proposed proprietary name / brand name	Omsaf 40mg capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Omeprazole enteric coated pellets eq to omeprazole…… 40mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	Alu-Alu Blisters containing 2×7 capsules
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Risek Capsule 40mg by M/s Getz Pharma
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference

		standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and comparative dissolution	Firm has submitted Pharmaceutical Equivalence and comparative dissolution with Risek Capsule 40mg (Getz Pharma)
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.		
API Lot Number	OMP1218		
Description of Pack (Container closure system)	2Alu-Alu Blisters, 7Capsule/Blister, in Unit Carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-016	TR-017	TR-018
Batch Size	1500 Capsule	1500 Capsule	1500 Capsule
Manufacturing Date	08-2022	08-2022	08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP (Certificate No. 3-26/2019-Addl.Dir.(QA&LT-1)-56 valid up to 13-06-2024 issued by QA&LT, DRAP Islamabad
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of locally purchased from M/s Vision Pharmaceuticals dated 14-06-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

645.	Name, address of Applicant / Marketing Authorization Holder	M/s Safina Pharmaceutical (Pvt) Ltd, 17 km. Sheikhupura Road, Lahore

	Name, address of Manufacturing site.	M/s Safina Pharmaceutical (Pvt) Ltd, 17 km. Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer
	GMP status of the firm	New DML dated 09-06-2021
	Evidence of approval of manufacturing facility	Capsule (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 1-43/2006-Lic(vol-I), dated: 10-06-2021
	Status of application	☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ **Domestic sale**
	Dy. No. and date of submission	15th, 2024, 3:46 pm
	Details of fee submitted	Rs. 30,000/- **dated** Jan 15, 2024 Slip No. 7883677030
	The proposed proprietary name / brand name	Omsaf 20mg capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Omeprazole enteric coated pellets eq to omeprazole…… 20mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	Alu-Alu Blisters containing 2×7 capsules
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	UL-Rid 20mg Capsule (Reg. # 026793)
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.

	Module-III Drug Product:	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and comparative dissolution	Firm has submitted Pharmaceutical Equivalence and comparative dissolution with Risek Capsule 20mg (Getz Pharma)
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.		
API Lot Number	OMP1218		
Description of Pack (Container closure system)	2Alu-Alu Blisters, 7Capsule/Blister, in Unit Carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-013	TR-014	TR-015
Batch Size	1500 Capsule	1500 Capsule	1500 Capsule
Manufacturing Date	08-2022	08-2022	08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP (Certificate No. 3-26/2019-Addl.Dir.(QA&LT-1)-56 valid up to 13-06-2024 issued by QA&LT, DRAP Islamabad
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of locally purchased from M/s Vision Pharmaceuticals dated 14-06-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
646.	Name, address of Applicant / Marketing Authorization Holder	M/s Aspin Pharma Private Limited, Plot # 10 & 25, Main Korangi Industrial road, Sector 20, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Aspin Pharma Private Limited, Plot # 10 & 25, Main Korangi Industrial road, Sector 20, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP inspection report based on inspection conducted on 09-02-2022 concluded good level of GMP compliance.
	Evidence of approval of manufacturing facility	Tablet (General) section confirmed vide letter No. F. 2-1/2005-Lic (Vol-II) dated 16-06-2021
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23669 dated 22-08-2022
	Details of fee submitted	PKR 30,000/- Dated 22-07-2022 Slip No. 031340386
	The proposed proprietary name / brand name	**Vazan Tablet 10mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan Fumarate equivalent to Vonoprazan …….10mg
	Pharmacotherapeutic Group of (API)	Potassium Competitive acid Blocker (P-CAB)
	Pharmaceutical form of applied drug	Light yellow coloured, film coated tablet
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab Tablet 10mg by Takeda Pharmaceutical Company Limited (PMDA Approved)
	For generic drugs (me-too status)	Vocinti Tablet 10mg (Reg. No. 108835) of M/s The Searle Company Limited.
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co Ltd. Jiangxi Fengxin Industrial Park, Fengxin Jiangxi Province Peoples Republic of China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure

		system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 24 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence of their product against the innovator's product Takecab Tablet 10mg Firm has submitted CDP results of their product against the innovator's product Takecab Tablet 10mg (batch No. 511956) in 3 pH 1.2 HCl buffer, pH 4.5 Acetate buffer, pH 6.8 Phosphate buffer.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	Jiangxi Synergy Pharmaceutical Co Ltd. Jiangxi Fengxin Industrial Park, Fengxin Jiangxi Province Peoples Republic of China		
API Lot No.	20211101BD		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3(Months) Real Time: 0, 3 (Months)		
Batch No.	277DS01	277DS02	277DS03
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	22-02-2022	22-02-2022	22-02-2022

No. of Batches		03
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 2022001) dated 20-01-2022 Validity 19-01-2027.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 22-12-2021 cleared on 24-01-2022 specifying 0.75Kg of Vonoprazan Fumarate. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted for initial and 3rd month time points.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not submitted**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S. No	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.1	Copy of the Drug substance specifications by Drug Product manufacturer is required.	Submitted
2.	3.2.S.4.2	Analytical procedures used for testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Submitted
3.	3.2.P.8	Accelerated and real time stability studies data is submitted till 3rd month time point, provide both accelerated and real time data upto 06 months supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

647.	Name, address of Applicant / Marketing Authorization Holder	M/s Aspin Pharma Private Limited, Plot # 10 & 25, Main Korangi Industrial road, Sector 20, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Aspin Pharma Private Limited, Plot # 10 & 25, Main Korangi Industrial road, Sector 20, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of GMP inspection report based on inspection conducted on 09-02-2022 concluded good level of GMP compliance.
	Evidence of approval of manufacturing facility	Tablet (General) section confirmed vide letter No. F. 2-1/2005-Lic (Vol-II) dated 16-06-2021
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23670 dated 22-08-2022
	Details of fee submitted	PKR 30,000/- Dated 22-07-2022 Slip No. 95689300197
	The proposed proprietary name / brand name	**Vazan Tablet 20mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan Fumarate equivalent to Vonoprazan …….20mg
	Pharmacotherapeutic Group of (API)	Potassium Competitive acid Blocker (P-CAB)
	Pharmaceutical form of applied drug	Pale pink coloured, film coated tablet
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab Tablet 20mg by Takeda Pharmaceutical Company Limited (PMDA Approved)
	For generic drugs (me-too status)	Vocinti Tablet 20mg (Reg. No. 108836) of M/s The Searle Company Limited.
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co Ltd. Jiangxi Fengxin Industrial Park, Fengxin Jiangxi Province Peoples Republic of China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real

		time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 24 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence of their product against the innovator's product Takecab Tablet 20mg Firm has submitted CDP results of their product against the innovator's product Takecab Tablet 20mg (batch No. 513186) in 3 pH 1.2 HCl buffer, pH 4.5 Acetate buffer, pH 6.8 Phosphate buffer.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	Jiangxi Synergy Pharmaceutical Co Ltd. Jiangxi Fengxin Industrial Park, Fengxin Jiangxi Province Peoples Republic of China		
API Lot No.	20211101BD		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3(Months) Real Time: 0, 3 (Months)		
Batch No.	278DS01	278DS02	278DS03
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	-	-	-
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 2022001) dated 20-01-2022 Validity 19-01-2027.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 22-12-2021 cleared on 24-01-2022 specifying 0.75Kg of Vonoprazan Fumarate. The invoice is cleared by AD (I&E) DRAP, Karachi.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted for 3rd month time point only.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not submitted**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S. No	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.1	Copy of the Drug substance specifications by Drug Product manufacturer is required.	Submitted
2.	3.2.S.4.2	Analytical procedures used for testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Submitted
3.	3.2.P.8	Accelerated and real time stability studies data is submitted till 3rd month time point, provide both accelerated and real time data upto 06 months supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Routine application of Form 5F (human) cases

648.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate dated 26-02-2020 issued on the basis of inspection conducted on 13-02-2020.
	Evidence of approval of manufacturing facility	Tablet General Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25243 dated 06-09-2022

	Details of fee submitted	Rs. 30,000/-: dated 15/08/2022.
	The proposed proprietary name / brand name	**Vonomark 10 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan as Fumarate….10mg
	Pharmacotherapeutic Group of (API)	Potassium-Competitive acid Blocker (P-CAB)
	Pharmaceutical form of applied drug	Light yellow round biconvex film coated tablets, plain from both sides
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab by Takeda is Approved in PMDA Japan
	For generic drugs (me-too status)	Vocinti Tablet 10mg (Reg. No. 108835) of M/s The Searle Company Limited.
	Name and address of API manufacturer.	M/s Jiangxi Synergy Pharmaceutical Co Ltd. Jiangxi Fengxin Industrial Park, Fengxin Jiangxi Province Peoples Republic of China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance .
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 09 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence of their product against the product Vonozan 10mg Tablet of M/s Getz Pharma.

		Firm has submitted CDP results of their product against the comparator's product Vonozan Tablet 10mg (batch No. 004FF8) of M/s Getz Pharma in 3 pH 1.2 HCl buffer, pH 4.5 Acetate buffer, pH 6.8 Phosphate buffer.
	Analytical method validation/verification of product	Submitted

STABILITY STUDY DATA

Manufacturer of API	Jiangxi Synergy Pharmaceutical Co Ltd. Jiangxi Fengxin Industrial Park, Fengxin Jiangxi Province Peoples Republic of China		
API Lot No.	20210801BD		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3(Months) Real Time: 0, 3 (Months)		
Batch No.	22VPL001	22VPL002	22VPL003
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	14-04-2022	14-04-2022	14-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 2022002) dated 12-03-2020 valid upto 11-03-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not submitted**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted for initial and 3rd month time point only.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not submitted**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not submitted**

Remarks of Evaluator:

S. No	Sections	Observations/Deficiencies/ Short-comings	Firm Reply
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted. Evidence of approval of manufacturing facility/ approved section from Licensing Authority.	GMP certificate dated 22-01-2024 is submitted. Submitted
2.	3.2.S.7	Only 09-month real time stability studies data of	Submitted upto 36 months

		drug substance is submitted, submit real time stability studies of drug substance upto 2 years.	
3.	3.2.P.5.2	Dissolution test parameters are mentioned as 30 minutes sampling time and Phosphate buffer (pH 6.8) medium whereas the acceptance limit of innovator product is testing at 15 minutes and 0.05M Acetate buffer (pH 4.5), Justify.	We have taken PMDA Japan approved product as innovator wherein details of dissolution specifications have not been revealed hence we follow the general pharmacopeia guideline for dissolution specifications and parameters for immediate release tablets. Moreover, the product approved by USFDA containing vonoprazan is a combo pack product while the applied product formulation is single unit tablet of vonoprazan.
4.	3.2.P.8	Accelerated and real time stability studies data is submitted for upto 3rd month time point, provide both accelerated and real time data upto 06 months supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. Compliance Record of HPLC software 21CFR & audit trail reports on product testing Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.
5.	3.2.P.8.3	Documents for the procurement of API with approval from DRAP (in case of import).	DRAP permission letter dated 18-09-2020 from AD (I&E) is submitted along with invoices.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

649.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sunder Industrial Estate, Lahore.
	Name, address of Manufacturing site.	M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate dated 26-02-2020 issued on the basis of inspection conducted on 13-02-2020.
	Evidence of approval of manufacturing facility	Tablet General Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26104 dated 14-09-2022

	Details of fee submitted	Rs. 30,000/-: dated 15/08/2022.
	The proposed proprietary name / brand name	**Vonomark 20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan as Fumarate….20mg
	Pharmacotherapeutic Group of (API)	Potassium-Competitive acid Blocker (P-CAB)
	Pharmaceutical form of applied drug	White to off-white round biconvex film coated tablets, plain from both sides
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab by Takeda is Approved in PMDA Japan
	For generic drugs (me-too status)	Vocinti Tablet 20mg (Reg. No. 108836) of M/s The Searle Company Limited.
	Name and address of API manufacturer.	M/s Jiangxi Synergy Pharmaceutical Co Ltd. Jiangxi Fengxin Industrial Park, Fengxin Jiangxi Province Peoples Republic of China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance .
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 09 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence of their product against the product Vonnp 20mg Tablet of M/s Horizon Pharmaceutical.

		Firm has submitted CDP results of their product against the comparator's product Vonnp 20mg Tablet of M/s Horizon Pharmaceutical (batch No. 156) in 3 pH 1.2 HCl buffer, pH 4.5 Acetate buffer, pH 6.8 Phosphate buffer.
	Analytical method validation/verification of product	Submitted

STABILITY STUDY DATA

Manufacturer of API	Jiangxi Synergy Pharmaceutical Co Ltd. Jiangxi Fengxin Industrial Park, Fengxin Jiangxi Province Peoples Republic of China		
API Lot No.	20210801BD		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3(Months) Real Time: 0, 3 (Months)		
Batch No.	22VPH001	22VPH002	22VPH003
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	20-04-2022	20-04-2022	20-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 2022002) dated 12-03-2020 valid upto 11-03-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not submitted**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted for initial and 3rd month time point only.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not submitted**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not submitted**

Remarks of evaluator:

S. No	Sections	Observations/Deficiencies/ Short-comings	Firm Reply
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted. Evidence of approval of manufacturing facility/ approved section from Licensing Authority.	GMP certificate dated 22-01-2024 is submitted. Submitted
2.	3.2.S.7	Only 09-month real time stability studies data	Submitted upto 36 months

		of drug substance is submitted, submit real time stability studies of drug substance upto 2 years.	
3.	3.2.P.2.2.1	Specify reference/comparator brand against which pharmaceutical equivalence and comparative dissolution has been performed, since you mentioned Vonnp 20mg tablet of M/s Horizon Pharmaceutical, whereas Vonnp could not be confirmed as registered brand name of M/s Horizon Pharmaceutical.	Vonnp 20mg Tablet of M/s Horizon Pharmaceutical.
4.	3.2.P.5.2	Dissolution test parameters are mentioned as 30 minutes sampling time and Phosphate buffer (pH 6.8) medium whereas the acceptance limit of innovator product is testing at 15 minutes and 0.05M Acetate buffer (pH 4.5), Justify.	We have taken PMDA Japan approved product as innovator wherein details of dissolution specifications have not been revealed hence we follow the general pharmacopeia guideline for dissolution specifications and parameters for immediate release tablets. Moreover, the product approved by USFDA containing vonoprazan is a combo pack product while the applied product formulation is single unit tablet of vonoprazan.
5.	3.2.P.8	Accelerated and real time stability studies data is submitted for upto 3rd month time point, provide both accelerated and real time data upto 06 months supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. Compliance Record of HPLC software 21CFR & audit trail reports on product testing Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.
6.	3.2.P.8.3	Documents for the procurement of API with approval from DRAP (in case of import).	DRAP permission letter dated 18-09-2020 from AD (I&E) is submitted along with invoices.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

650.	Name, address of Applicant / Marketing Authorization Holder	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone 26-Km Lahore Sharikpur Road, Sheikhupura.
	Name, address of Manufacturing site.	Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone 26-Km Lahore Sharikpur Road, Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP inspection report dated 05-12-2022

	Evidence of approval of manufacturing facility	Tablet Section (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 1-1/2016-Lic, dated: 24-02-2020.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 25509 dated 08-09-2022
	Details of fee submitted	Rs. 30,000/- dated 02-09-2022 Slip No. 710134869597
	The proposed proprietary name / brand name	**Levofloxacin 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin Hemihydrate eq. to Levofloxacin ….250mg
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotic ATC code: J01MA12
	Pharmaceutical form of applied drug	Slightly yellow colored oblong, biconvex film-coated tablet, word "variant" is engraved on one side and the other side is plain
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levofloxacin 250mg Tablet (USFDA Approved)
	For generic drugs (me-too status)	Leflox Tablets 250mg (Reg. No.: 026164) of M/s Getz Pharma (Pvt.) Limited, Karachi
	Name and address of API manufacturer.	M/s Aarti Drugs Limited – India Address: Plot No. E-120/119/105/106/104, M.I.D.C. Tarapur, Boisar, Tal-palghar, Dist. Thane 401506 MH India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches

	(Conditions & duration of Stability studies)	of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence of their product against the product Tavanic 250mg Tablets (Batch No. AW002) manufactured by M/s Sanofi-Aventis Pakistan. Firm has submitted Comparative Dissolution Profile of their product against the reference product Tavanic 250mg Tablets (Batch No. AW002) manufactured by M/s Sanofi-Aventis Pakistan.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Aarti Drugs Limited – India Address: Plot No. E-120/119/105/106/104, M.I.D.C. Tarapur, Boisar, Tal-palghar, Dist. Thane 401506 MH India.		
API Lot No.	LFC/11010006		
Description of Pack (Container closure system)	10 tablets in Alu-Alu Blisters packed in cardboard unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	11-2021	11-2021	11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP (Certificate No. NEW-WHO-GMP/CERT/KOl 11037 012022111 140429) valid up to 18-05-2025 issued by Food & Drug Administration. M.S Bandra-kurla Complex, Bandra (E), Mumbai Maharashtra, India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EXP/3123/22-21 dated 03-08-2021 cleared on 06-09-

		2021 specifying 5.00 Kg. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not submitted**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S. No	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	GMP inspection report dated 05-12-2022
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Submitted
3.	3.2.S.4.2	Analytical procedures used for testing of the Drug substance by Drug Product manufacturer is required.	Submitted
4.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.	Firm inform that they use same formulation as reference product of M/s Accord Health Care UK as per following details:
5.	3.2.P.8	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

Variant Pharma	Accord UK
Avicel 102(known as	Cellulose Microcrystalline
PVPK30 (Know as povidone)	Povidone
Cross povidone	Cross povidone
Magnesium stearate	Magnesium stearate
Aerosil 200 (Know as silica colloidal)	Silica colloidal anhydrous

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

651.	Name, address of Applicant / Marketing Authorization Holder	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone 26-Km Lahore Sharikpur Road, Sheikhupura.
	Name, address of Manufacturing site.	Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone 26-Km Lahore Sharikpur Road, Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP inspection report dated 05-12-2022
	Evidence of approval of manufacturing facility	Tablet Section (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 1-1/2016-Lic, dated: 24-02-2020.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 25510 dated 08-09-2022
	Details of fee submitted	Rs. 30,000/- dated 02-09-2022 Slip No. 89451109888
	The proposed proprietary name / brand name	**Levofloxacin 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin Hemihydrate eq. to Levofloxacin ….500mg
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotic ATC code: J01MA12
	Pharmaceutical form of applied drug	Slightly yellow colored oblong, biconvex film-coated tablet, word "variant" is engraved on one side and bisect line on the other side
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levofloxacin 500mg Tablet (USFDA Approved)
	For generic drugs (me-too status)	Leflox Tablets 500mg (Reg. No.: 026163) of M/s Getz Pharma (Pvt.) Limited, Karachi
	Name and address of API manufacturer.	M/s Aarti Drugs Limited – India Address: Plot No. E-120/119/105/106/104, M.I.D.C. Tarapur, Boisar, Tal-palghar, Dist. Thane 401506 MH India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence of their product against the product Tavanic 500mg Tablets (Batch No. AH002) manufactured by M/s Sanofi-Aventis Pakistan. Firm has submitted Comparative Dissolution Profile of their product against the reference product Tavanic 500mg Tablets (Batch No. AH002) manufactured by M/s Sanofi-Aventis Pakistan.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Aarti Drugs Limited – India Address: Plot No. E-120/119/105/106/104, M.I.D.C. Tarapur, Boisar, Tal-palghar, Dist. Thane 401506 MH India.		
API Lot No.	LFC/11010006		
Description of Pack (Container closure system)	10 tablets in Alu-Alu Blisters packed in cardboard unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	11-2021	11-2021	11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP (Certificate No. NEW-WHO-GMP/CERT/KOl 11037 012022111 140429) valid up to 18-05-2025 issued by Food & Drug Administration. M.S Bandra-kurla Complex, Bandra (E), Mumbai Maharashtra, India.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EXP/3123/22-21 dated 03-08-2021 cleared on 06-09-2021 specifying 5.00 Kg. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not submitted**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S. No	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	GMP inspection report dated 05-12-2022
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Submitted
3.	3.2.S.4.2	Analytical procedures used for testing of the Drug substance by Drug Product manufacturer is required.	Submitted
4.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.	Firm inform that they use same formulation as reference product of M/s Accord Health Care UK as per following details:
5.	3.2.P.8	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

Variant Pharma	Accord UK
Avicel 102(known as	Cellulose Microcrystalline
PVPK30 (Know as povidone)	Povidone
Cross povidone	Cross povidone
Magnesium stearate	Magnesium stearate
Aerosil 200 (Know as silica colloidal)	Silica colloidal anhydrous

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case no. 06 Registration applications of import cases (Short molecule)

652.	**Name, address of Applicant / Importer**	**M/s** Xeno Biotech Pharma and Devices (Distributors), House No.43-A, Stree # 5-F, Near Bank Al-Falah Tulsa Road, Lala Zar Rawalpindi Cantt.

	Details of Drug Sale License of importer	**License No:** 01-374-0176-112407D **Address:** House No.43-A, Stree # 5-F, Near Bank Al-Falah Tulsa Road, Lala Zar Rawalpindi Cantt. **Address of Godown:** NA **Validity:** 06-01-2029. **Status:** License to sell drugs as distributor **Renewal:** N/A
	Name and address of marketing authorization holder (abroad)/Manufacturer	**M/s** Celon Laboratories Private Limited Plot No.2, ALEAP Industrial Estate, Gajularamaram, Medchal-Malkajgiri Dist. 500 090, Telangana State, India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** No. 4263097/TS/2024 issued by Drug Control Administration, Government of Telangana valid upto 11-06-2025.
	Details of letter of authorization / sole agency agreement	Letter of Authorization from Product license holder is submitted.
	Status of the applicant	☒ Importer
	Status of application	☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale
	For imported products, specify one the these	☒ Finished Pharmaceutical product import
	Dy. No. and date of submission	January 22nd, 2024, 6:42 pm
	Details of fee submitted	PKR 3,00,000/- Dated Jan 22, 2024 Challan No. 01845360965
	The proposed proprietary name / brand name	Hypro 200 Injection 20ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contain: Propofol .....10mg.
	Pharmaceutical form of applied drug	IV Injection
	Pharmacotherapeutic Group of (API)	Anesthetics, ATC Code N01AX10
	Reference to Finished product specifications	USP
	Proposed Pack size	20ml Vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Diprivan 10 mg/ml (1%) Emulsion for injection
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Neuland Laboratories Limited. Sanali Info Park, Block A, Ground floor, 8-2-120/113, Road No.2, Banjara Hills. Hyderabad

		– 500 034. Telangana, India. 091-40-30211600, 23551081 091-40-30211602
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 2-8°C for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of critical steps and intermediate products, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence report against the innovator product Diprivan
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	20 mL clear USP type-I moulded vial sealed with 20 mm grey colored bromo butyl plain rubber stopper and blue colored 20 mm aluminium flip off seal
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 24months as per Zone IVb as per following details: Long-term 24 months (30°C ± 2°C / 75% RH ± 5% RH) and Accelerated 6 months (40°C ± 2°C / 75% RH ± 5% RH) storage condition
Decision: Approved as per policy of inspection of manufacturer abroad.		

Cases of New License / New Section

M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.

164.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Evidence of approval of manufacturing facility	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. EDZ-B4V-N9M8: 25-04-2024
	Details of fee submitted	PKR 30,000/-: 22-04-2024
	The proposed proprietary name / brand name	**MEEAN 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Piroxicam Beta Cyclodextrin Eq. to Piroxicam……...20mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	NSAID

	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Brexin Tablet (**ANSM France** Approved)
	For generic drugs (me-too status)	Woxicam 20mg Tablet (Warafana Pharmaceuticals) Reg. 072300
	Name and address of API manufacturer.	Nantong Jinghua Pharmaceutical Co Ltd No 20, 3 Haibin Road Yanhai Economic Development Zone Rudong Jiangsu China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Felbex tablet of Martin Dow. Firm has submitted results of CDP for their product against Felbex tablet of Martin Dow
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Nantong Jinghua Pharmaceutical Co Ltd No 20, 3 Haibin Road Yanhai Economic Development Zone Rudong Jiangsu China.

API Lot No.	20211206		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PBCD-TAB-001	PBCD-TAB-002	PBCD-TAB-003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	10-2023	10-2023	10-2023
Date of Initiation	06-10-2023	06-10-2023	06-10-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted manufacturing license of the firm issued by NMPA China valid till 13-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted clearance certificate of M/s De-Mont Research Lab dated 12-06-2022. Firm has also submitted copy of loan letter.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted by the firm
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit copy of loan letter

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

165.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Evidence of approval of manufacturing facility	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. 3L1-UVZ-74QS: 25-04-2024
	Details of fee submitted	PKR 30,000/-: 22-04-2024
	The proposed proprietary name / brand name	**Atfonac 3ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 3ml Ampoule Contains: Diclofenac Sodium ……75mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Dicloran Injection by Sami
	Name and address of API manufacturer.	Henan Dongtai Pharma Co Ltd No. 2, Est Kangtai Road, Tangyin Anyang Henan China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure

		system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Dicloran Injection of Sami Pharma
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Henan Dongtai Pharma Co Ltd No. 2, Est Kangtai Road, Tangyin Anyang Henan China.		
API Lot No.	301221227-5		
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DS-INJ-001	DS-INJ-002	DS-INJ-003
Batch Size	500 ampoule	500 ampoule	500 ampoule
Manufacturing Date	10-2023	10-2023	10-2023
Date of Initiation	09-10-2023	09-10-2023	09-10-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by NMPA China valid till 05-11-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted ADC cleared invoice of M/s Treat Pharma dated 21-02-2023. Firm has also submitted copy of loan letter.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted by the firm
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit BMR of the stability batches

Decision: Approved

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

166.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Evidence of approval of manufacturing facility	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section

		• Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. ZQ7-R2P-H24L: 25-04-2024
	Details of fee submitted	PKR 30,000/-: 22-04-2024
	The proposed proprietary name / brand name	**HISTANEM 2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains: Pheniramine Maleate…….50 mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Antihistamine
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be confirmed
	For generic drugs (me-too status)	Ann-vil Injection by Venus Pharma
	Name and address of API manufacturer.	Supriya Lifescience Limited A-5/2, Lote Parshuram Industrial Area MIDC Taluka Ratnagiri Mahrashtra India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols,

		control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Amrovil Injection of Amros Pharma
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Supriya Lifescience Limited A-5/2, Lote Parshuram Industrial Area MIDC Taluka Ratnagiri Mahrashtra India		
API Lot No.	SLL/P/0221007		
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PM-INJ-001	PM-INJ-002	PM-INJ-003
Batch Size	500 ampoule	500 ampoule	500 ampoule
Manufacturing Date	10-2023	10-2023	10-2023
Date of Initiation	06-10-2023	06-10-2023	06-10-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted manufacturing license of the firm issued by NMPA China valid till 13-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted ADC cleared invoice of M/s Neutro Pharma dated 19-03-2021. Firm has also submitted copy of loan letter.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted by the firm
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC:		

• Evidence of approval of applied formulation in reference regulatory authorities which were adopted by the Board in its 275th meeting. • Submit copy of loan letter • Submit BMR of the stability batches
Decision: Deferred for the submission of shortcoming comunicated

167.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Evidence of approval of manufacturing facility	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. HR5-MZ9-4Y4Q: 24-04-2024
	Details of fee submitted	PKR 30,000/-: 18-04-2024
	The proposed proprietary name / brand name	**MURACEF 250mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Cefadroxil Monohydrate equivalent to Cefadroxil ……250mg
	Pharmaceutical form of applied drug	Capsule

	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be confirmed. 500mg capsule is available in USFDA however 250mg capsule is discontinued without specifying the reason for discontinuation.
	For generic drugs (me-too status)	Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan.
	Name and address of API manufacturer.	Henan Dongtai Pharma Co Ltd. No 2 Est Kangtai Road Tangyin Anyang Henan China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Dicloran Injection of Sami Pharma
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan.
API Lot No.	

Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DS-INJ-001	DS-INJ-002	DS-INJ-003
Batch Size	500 ampoule	500 ampoule	500 ampoule
Manufacturing Date	10-2023	10-2023	10-2023
Date of Initiation	09-10-2023	09-10-2023	09-10-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 18-11-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted clearance certificate of M/s Treat Pharma dated 21-02-2023. Firm has also submitted copy of loan letter.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted by the firm
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Evidence of approval of applied formulation in reference regulatory authorities which were adopted by the Board in its 275th meeting, since the submitted reference of China Food and Drug Administration is not a reference regulatory authority of DRAP.
- Submit module 3 for cefadroxil capsule since the submitted module 3 is of cefadroxil suspension.
- Submit BMR of the stability batches

Decision: Deferred for the submission of shortcoings comunicated

168.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.**
	Name, address of Manufacturing site.	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license dated 26-10-2023 for following sections:

		• Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Evidence of approval of manufacturing facility	Firm has been granted new license dated 26-10-2023 for following sections: • Tablet (General) section • Liquid injection vial (General) section • Liquid injection ampoule (general) section • Capsule (Cephalosporin) section • Dry powder for injection (cephalosporin) section • Dry powder for suspension (cephalosporin) section • Cream / ointment (General) section • Eye drops (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID. DX9-WB7-2D7Q: 25-04-2024
	Details of fee submitted	PKR 30,000/-: 19-04-2024
	The proposed proprietary name / brand name	**NAEMOL 1000mg/100ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vail contain: Paracetamol…….1000mg
	Pharmaceutical form of applied drug	Infusion
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Provas infusion by Sami
	Name and address of API manufacturer.	Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Acetamol infusion of Seraph pharma
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan.		
API Lot No.	00510941/363/2023		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	600 Bottles	600 Bottles	600 Bottles
Manufacturing Date	10-2023	10-2023	10-2023
Date of Initiation	08-10-2023	08-10-2023	08-10-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 18-11-2022.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 29-09-2023 specifying 3kg paracetamol
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted by the firm
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit verification studies of the drug substance performed by drug product manufacturer
- Submit COA of relevant batch of API from drug substance manufacturer as well as drug product manufacturer
- Copy of Batch Manufacturing Record of stability batches

Decision: Approved. Registration letter will be issued upon submission of following:

i. **Verification studies of the drug substance performed by drug product manufacturer**
ii. **COA of relevant batch of API from drug substance manufacturer as well as drug product manufacturer.**
iii. **Copy of Batch Manufacturing Record of stability batches**

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Registration-I Section

Case No.01. Extension in Validity of Registration of Flurocort Tablet 0.1% (Reg. No.108902)

In line with the decision taken by the DRAP's Authority in its 91st meeting (held on 04-09-2020) regarding priority registration of Fludrocortisone Tablet and in light of approvals granted by the reference regulatory authorities, Registration Board in its 296th meeting held on 08th-10th Sep, 2020 considered the application of M/s Tabros Pharma Pvt Ltd. L-20/B, Sector-22, Federal B Industrial Area, Karachi regarding registration of "Fludrocort (Fludrocortisone) 0.1mg Tablet" and decided as under:

> **"Approved for manufacturing in Tablet (Steroid) section. Registration letter will be processed after submission of differential fee of Rs. 30,000/-. The Board further decided that registration shall be valid for one (01) year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by registration Board in its 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration."**

Accordingly, registration letter was issued on 16-08-2021 as per following detail:

S. No.	Reg. No.	Name of Drug(s) & Composition
1.	108902	Flurocort Tablet 0.1mg Each tablet contains: Fludrocortisone Acetate……0.1mg (USP Specifications)

Registration shall be valid for 01 year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration.

Later on, the firm applied (vide Dy.No. 24076 dated 25-08-2022) for extension in validity of registration on the basis of following data/ information:

1.	Name, address of Applicant / Marketing Authorization Holder	M/s Tabros Pharma Pvt. Ltd. L-20/B, Sector-22, Federal B Industrial Area, Karachi
	Name, address of Manufacturing site.	M/s Tabros Pharma Pvt. Ltd. L-20/B, Sector-22, Federal B Industrial Area, Karachi
	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 and Export sale ☐ Export sale ☐ Domestic
	Dy. No. and date of submission	Dy. No.24076 dated 25.08.2022
	The proposed proprietary name / brand name	Flurocort Tablet 0.1mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Fludrocortisone Acetate …… 0.1mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Mineralocorticoid
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1's 2x10's
	The status in reference regulatory authorities	Florinef 0.1mg Tablet Aspen Pharma MHRA Approved
	For generic drugs (me-too status)	NA

	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conducted on 07-04-2022.
	Name and address of API manufacturer.	Farmabios S.p.A, Via Pavia 1, Gropello Cairoli 27027 Italy.
	Module-II (Quality Overall Summary)	Not submitted.
	Module III (Drug Substance)	Not submitted.
	Stability studies	Firm has submitted stability study data of API **(Fludrocortisone Acetate).** Stability study is conducted at Accelerated conditions; 40°C± 2°C& 75%±5%RH for 06 months and at real time conditions; 30°C ± 2°C & 75% ± 5% RH for 36 months at intervals 0, 1, 3 & 6 months and 0, 3, 6, 9, 12, 18, 24 & 36 months respectively. Batches:(2142AM0 B0011523, 2142AM0 B0011623, 2142AM0 B0021623)
	Module-III (Drug Product):	Firm has submitted information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of critical steps and intermediate, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the reference product Florinef 0.1mg tablet by M/s. Aspen Pharma Pty Ltd, by performing quality tests including Appearance, average weight, Assay, Dissolution, Disintegration. CDP has been performed against the reference product that is FLORINEF TABLET 0.1mg tablet of Aspen Pharma Pty Ltd in Acid media (0.1N HCl), acetate buffer pH 4.5, Phosphate Buffer pH 6.8 & 0.01N HCl (QC Medium). The F2 values are found satisfactory
	Analytical method validation / verification of product	Method verification studies have submitted including linearity, range, accuracy, precision & specificity.

STABILITY STUDY DATA

Manufacturer of API	Farmabios S.p.A, Via Pavia 1, Gropello Cairoli, 27027.
API Lot No.	2142AMO B0011923
Description of Pack (Container closure system)	2x10's Alu-PVC 1's Alu-PVC

Stability Storage Condition	Real time: 30°C ±2° C/RH/ 65%±5% Accelerated: 40 °C± 2° C /RH 75%±5%		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9. 12, 18, 24 (months)		
Strength	Flurocort Tablet 0.1mg		
Batch No.	001	002	003
Batch Size	150000 Tablets	150000 Tablets	150000 Tablets
Manufacturing Date	Oct-2021	Dec-2021	Feb. 2022
Date of Initiation	Nov.-2021	20-12-2021	10.02.2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred last onsite panel inspection for instant dosage form conducted during last two years BAXIB (Apixaban) 2.5mg & 5mg Tablets on 5th January, 2021 by following panel: 1. Prof. Dr. Rafeeq Alam Khan, Dean, Faculty of Pharmacy, Zia Uddin University, Karachi. (Member Registration Board). 2. Dr. Saif-ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate from AIFA Italy has submitted. The certificate valid till 01.10.2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice of Fludrocortisone Acetate dated:05.12.2019 in the name of FARMABIOS Via Pavia, 1-27027 Gropello Caroli PV, Italy attested by ADC DRAP Karachi. ADC signed Form 6 is attached while Form 3 and Form 7 are also available.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator	Response Received from Registration Holder
Qualitative composition of reference product i.e., MHRA approved Florinef 0.1mg Tablet by Aspen Pharma and applied formulation are different. Accordingly, Drug-excipient compatibility studies are required to be submitted.	We have been developed our product with the Reference from Amneal Pharmaceuticals New York LLC, Link is given below for your ready reference, While, CDP and Pharmaceutical Equivalence were performed against the Florinef 0.1mg Tablets- Aspen Pharma, MHRA approved, Additionally, we have found satisfactory results on stability up to the shelf life. Based on the fact that it is clearly indicated that our product is complying with the Florinef 0.1 mg Tablets, as similar as Innovator pack. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=51363453-6d33-4aee-8426-37ac0bf3cc10. Drug-Excipient compatibility studies have also been submitted.
Description of Container Closure System is not mentioned on provided stability data. Furthermore, Alu-Alu Blister is mentioned in Stability Study Protocol. Pl. clarify.	Now mentioned Container Closure system in stability data (Please find attached revised stability data), However, Alu-Alu blister was given by mistaken in stability study Protocol, while other data like Pharmaceutical Development has mentioned Alu-PVC blister accordingly.

Keeping in view that "Flurocort Tablet 0.1mg" is the only registered product containing "Fludrocortisone" which is used for treatment of rare condition "Addison's Disease", above application is submitted for consideration of Registration Board.

Decision: **Registration Board decided to regularize the registration of "Flurocort (Fludrocortisone Acetate) Tablet 0.1mg (Reg. No. 108902)" for a period of five years from the date of issuance of registration letter as per law. Accordingly, renewal application shall be submitted from initial date of registration i.e., 16-08-2021.**

Import &Vet-I Section

Recommendations of Sub-Committee on Veterinary Drugs

Case No. 1 Details of Seven molecule containing products refer to Expert group on veterinary drugs in different meeting of Registration Boards

Registration Board in its 331st meeting directed the sub-committee to review following molecules containing products which are under show cause in different meeting of Registration Board;

i. Chloramphenicol for Veterinary Use.

International status of Chloramphenicol containing formulations from official website of USFDA accessed on dated 05-03-2021 Animal Drugs @ FDA.
In all dosage forms.

All listed product shows status: Prescription and Approved

Sr. #	Manufacturer	Brand Name & Composition	Indication	Target Animal
1.	Cronus Pharma Specialities India Private Limited Sy No: 99/1, M/s GMR Hyderabad Aviation SEZ L Mamidipalli	**TEVCOCIN-chloramphenicol liquid** Each milliliter contains 100 milligrams of chloramphenicol.	Treatment of infections of the respiratory tract, the urinary tract, and enteritis and tonsillitis caused by	Dogs

	Village,Shamshabad Mandal, Ranga Hyderabad, Telangana 501218 India		organisms susceptible to chloramphenicol.	
2.	Zoetis Inc. 333 Portage St. Kalamazoo, Michigan 49007	**CHLOROMYCETIN PALMITATE ORAL SUSPENSION** Each milliliter contains chloramphenicol palmitate equivalent to 30 milligrams of chloramphenicol	Treatment of bacterial pulmonary infections, infections of the urinary tract, enteritis, and infections associated with canine distemper that are caused by organisms susceptible to chloramphenicol.	Dogs
3.	Zoetis Inc. 333 Portage St. Kalamazoo, Michigan 49007	**CHLOROMYCETIN TABLETS 250 MG-chloramphenicol table** Each tablet contains 100, 250, or 500 milligrams of chloramphenicol.	Oral treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.	Dogs
4.	Bimeda Animal Health Limited 1B The Herbert Building The Park Carrickmines, Dublin 18, Ireland	VICETON® TABLETS-chloramphenicol tablet Each tablet contains 50, 100, 250, or 500 milligrams, or 1 gram of chloramphenicol.	Oral treatment of bacterial gastroenteritis associated with bacterial diarrhea, bacterial pulmonary infections, and bacterial infections of the urinary tract caused by susceptible organisms.	Dogs
5.	Zoetis Inc. 333 Portage St. Kalamazoo, Michigan 49007	CHLOROMYCETIN OPHTHALMIC OINTMENT Each gram contains 10 milligrams of chloramphenicol.	Dogs Treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol. Cats Treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol.	Cats (Domestic) Dogs
6.	Pharmaceutical Ventures, Ltd. P.O. Box D1400 Pomona, New York 10970 United States	CHLORAMPHENICOL CAPSULES Each capsule contains 50, 100, 250 and 500 milligrams chloramphenicol.	Oral treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis and bacterial infections associated with canine distemper caused by susceptible organisms	Dogs
7.	Dechra, Ltd. Snaygill Industrial Estate Keighley Rd. Skipton, North Yorkshire BD23 2RW United Kingdom	CHLORAMPHENICOL 1% OPHTHALMIC Each gram contains 10 milligrams chloramphenicol.	Cats Treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol. Dogs Treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol.	Cats (Domestic) Dogs

8.	Zoetis Inc. 333 Portage St. Kalamazoo, Michigan 49007	MYCHEL-VET INJECTION Each milliliter contains 100 milligrams of chloramphenicol.	Treatment of infections of the respiratory tract, the urinary tract, and enteritis and tonsillitis caused by organisms susceptible to chloramphenicol.	Dogs

Recommendation of Sub-committee:
After deliberation, the Sub-committee on Veterinary Drugs observed that the use of chloramphenicol is prohibited in the EU, Australia, Canada, and other Reference Regulatory Authorities (RRA) for veterinary purposes, except for its rare use in cats and dogs. The committee deliberated that safer and more effective alternatives, such as Florfenicol, are freely available. Therefore, the Committee recommends restricting the use of chloramphenicol in veterinary medicine due to its potential risk of abuse in food-producing animals and public health hazards. Additionally, the Committee recommends de-registering all formulations containing chloramphenicol.

Decision:
The Registration Board deliberated on recommendation of the Sub-committee on Veterinary Drugs regarding prohibition of chloramphenicol in EU, Australia, Canada and other Reference Regulatory Authorities (RRA) for veterinary purposes, except for its rare use in cats and dogs. Hence Board restricted the use of chloramphenicol in veterinary medicine due to its potential risk of abuse in food-producing animals & public health hazards and decided to issue show cause notices to the firms holding registrations of "chloramphenicol for veterinary use only" for cancellation of registration under Section 42 of the Drugs Act, 1976.

ii. Phenylbutazone for veterinary use.

International status of Phenylbutazone containing formulations from official website of USFDA accessed on dated 05-03-2021 Animal Drugs @ FDA
All listed product shows status: Prescription and Approved

Sr. #	Manufacturer	Brand Name & Composition	Indication	Target Animal
1.	Intervet, Inc. 2 Giralda Farms Madison, New Jersey 07940 United States	Butazolidin® Bolus Butazolidin® Tablets	Dogs The drug is used for the relief of inflammatory conditions associated with a musculoskeletal system. Horses This drug is used for the relief of inflammatory conditions associated with the musculoskeletal system.	Equids : Horse Dog
2.	Intervet, Inc. 2 Giralda Farms Madison, New Jersey 07940 United States	Butazolidin® Injectable 20% The drug contains 200 milligrams of phenylbutazone in each milliliter of sterile aqueous solution.	Horses It is used for the relief of inflammatory conditions associated with the musculoskeletal system. Dogs It is used for the relief of inflammatory conditions associated with the musculoskeletal system.	Equids : Horse Dogs :
3.	Intervet, Inc. 2 Giralda Farms Madison, New Jersey 07940 United States	Butazolidin® Granules The drug is in granular form. It is packaged to contain 8 grams of phenylbutazone per package.	Horses For the treatment of inflammatory conditions associated with the musculoskeletal system.	Equids : Horse
4.	Cronus Pharma Specialities India Private Limited	Phenylbutazone Tablets, USP 100 &200 mg	Dogs For the relief of inflammatory conditions associated with the musculoskeletal system	Dogs

	Sy No: 99/1, M/s GMR Hyderabad Aviation SEZ L Mamidipalli Village,Shamshabad Mandal, Ranga Hyderabad, Telangana 501218 India	Each tablet contains 100mg & 200 milligrams Phenylbutazone USP.		

Recommendation of Sub-committee:
After deliberation, the sub-committee on Veterinary Drugs observed that since Phenylbutazone is primarily used in non-food-producing animals in Reference Regulatory Authorities (RRA), its use should be restricted to these animals only. Furthermore, a prominent warning on the label of drug products containing Phenylbutazone, restricting its use in equine animals, should also be shown clearly.

Decision:
The Registration Board deliberated on recommendation of Sub-committee on Veterinary Drugs regarding use of Phenylbutazone primarily in non-food-producing animals in Reference Regulatory Authorities (RRA) and its use should be restricted to these animals only. Furthermore, a prominent warning on the label of drug products containing Phenylbutazone, restricting its use in equine animals, should also be shown clearly.

iii. Furazolidone for Veterinary Use.

International status of Furazolidone l containing formulations from official website of USFDA accessed on dated 10-03-2021 Animal Drugs @ FDA
All listed product shows status: Prescription and Approved

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

Recommendation of 09th EWG:-
The Expert Working Group on Veterinary Drugs decided to recommend to de-register all the registered veterinary formulations containing Furazolidone due to strong potential of causing genotoxicity, cytotoxicity and possible residual effects.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs observed that the use of furazolidone is prohibited in the EU, Australia, Canada, and other Regulatory Reference Authorities (RRA) for veterinary purposes, except for its rare use in non-food-producing animals. The committee decided to recommend the deregistration of all veterinary formulations containing Furazolidone due to its strong potential for causing genotoxicity, cytotoxicity, and possible residual effects.

Decision:
The Registration Board deliberated on the recommendation of Sub-committee on Veterinary Drugs regarding prohibition of furazolidone in the EU, Australia, Canada and other Regulatory Reference Authorities (RRA) for veterinary purposes, except for its rare use in non-food-producing animals. Registration Board decided to issue show cause notices to the firms holding registrations of "furazolidone for veterinary use only" for cancellation of registration under Section 42 of the Drugs Act, 1976 due to its strong potential for causing genotoxicity, cytotoxicity, and possible residual effects.

iv. Novaminsulfon/Dipyrone/ Metamizole for Veterinary Use.

DEPARTMENT OF MEDICINES VETERINARIANS SPAIN

1. BUSCAPINA COMPOSITUM VETERINARY USE solution for injection for horse.

Each ml contains:
Active substances:
Scopolamine butylbromide ..... 4.00 mg
(equivalent to 3.27 mg scopolamine)
Metamizole sodium .... 500.00 mg
(equivalent to 443.10 mg of metamizole

2. ESPASMODIAN solution for injection FOR Cattle and horses

Each ml contains:
Active substances:
Sodium metamyzole monohydrate..... 500.00 mg
(equivalent to 467.03 mg metamizol)
Scopolamine Butyl Bromide ..... 4.00 mg
(equivalent to 2.76 mg scopolamine)
Data access on 05-03-2021 from official website of Spanish authority .:: CIMAVET ::. Resultados de la búsqueda de medicamentos (aemps.es)

Recommendation of 10th EWG:-

The Expert Working Group on Veterinary Drugs recommended the cancellation of registration of already registered drugs containing salt Novaminsulfom/Dipyrone/ Metamizole for Veterinary drugs for being associated with serious adverse effects like agranulocytosis.

Recommendation of Sub-committee:
After deliberation, the Sub-committee on Veterinary Drugs observed that the EU veterinary medicine management establishes and allows the Maximum Residue Limit (MRL) of metamizole, permitting its use in Bovine and Equine. The sub-committee recommends adhering to the use of metamizole in accordance with EU regulations.

Decision:
The Registration Board deliberated on the recommendation of Sub-committee on Veterinary Drugs that the EU veterinary medicine management establishes and allows the Maximum Residue Limit (MRL) of metamizole, permitting its use in Bovine and Equine. Board recommends adhering to the use of metamizole in accordance with EU regulations.

v. Amantadine in combination with other antibiotics/ antibacterial for Veterinary Use.

No registration data available from official website of reference regulatory authority's data base.

Recommendation of 09th EWG:-

The Expert Working Group on Veterinary Drugs deliberated the matter and observed in absence of any recognized scientific rational, regarding simultaneous use of antibiotic with antiviral drugs, in any RRA all such combination are recommended to de-register in the best public health interest. Further the Group will further examine single amantadine containing formulations according to food safety/public health point of view and status in RRA.

Recommendation of Sub-committee:
The sub-committee on Veterinary Drugs deliberated on the matter and observed that, in the absence of any recognized scientific data regarding the use of amantadine in any Reference Regulatory Authority (RRA), all such combinations are recommended for deregistration in the best interest of public health.

Decision:

The Registration Board deliberated on the matter in detail and based on the recommendation of the Sub-committee on Veterinary Drugs decided that in the absence of any recognized scientific data regarding the use of amantadine by any Reference Regulatory Authority (RRA). Registration Board decided to issue show cause notices to the firms holding registrations of "Amantadine in combination with other antibiotics/ antibacterial for veterinary use only" for cancellation of registration under Section 42 of the Drugs Act, 1976. The Board further decided to allow only single amantadine containing formulations.

vi. Norfloxacin for Veterinary Use

No registration data available from official website of reference regulatory authority's data base.

Recommendation of 09th EWG:-
The Expert Working Group on Veterinary Drugs decided to recommend that ciprofloxacin and Norfloxacin should be used only in humans and recommended to de-register all formulations containing ciprofloxacin and Norfloxacin for veterinary use due to potential of AMR and in the best public health interest.

Recommendation of Sub-committee:
The sub-committee on Veterinary Drugs deliberated on the matter and observed that, in the absence of any recognized scientific data regarding the use of norfloxacin in any Reference Regulatory Authority (RRA), all such combinations are recommended may be forwarded to M/o NFS&R for their comments before deregistration in the best interest of public health.

Decision:
The Registration Board deliberated the matter in the details, keeping in view absence of any recognized scientific data regarding the use of norfloxacin in any Reference Regulatory Authority (RRA) and based on the recommendation of Sub-committee on Veterinary Drugs decided to refer all such combinations to M/o NFS&R for their comments for their valuable inputs.

vii. Furaltadone for Veterinary Use.

No registration data available from official website of reference regulatory authority's data base.

Recommendation of 09th EWG:
The Expert Working Group on Veterinary Drugs decided to recommend de-registering all the registered veterinary formulations containing Furaltadone due to strong potential of causing genotoxicity, cytotoxicity and possible residual effects.

Recommendation of Sub-committee:
The sub-committee on Veterinary Drugs deliberated on the matter and observed that, in the absence of any recognized scientific data regarding the use of Furaltadone in any Reference Regulatory Authority (RRA), all such combinations are recommended for deregistration in the best interest of public health.

Decision:
The Registration Board deliberated on the matter in detail, keeping in view absence of any recognized scientific data regarding the use of Furaltadone by any Reference Regulatory Authority (RRA) and based

on the recommendation of the Sub-committee on Veterinary Drugs, Registration Board decided to issue show cause notices to all the firm holding registrations of "Furaltadone for veterinary use only" for the cancellation of registration under section 42 of the Drugs Act, 1976 and rules framed thereunder.

Import & Vet-II Section/Human Import

Case No.01. REGISTRATION OF FREEFOL MCT 1% INJECTION 20ML VIAL (PROPOFOL 10MG/ML).

M/s Ghani Brothers, Karachi application approved in 330th meeting of Registration Board as per following details:-

Name of Importer / Product License Holder & Manufacturer	Name of Drug / Composition	Demanded Pack / MRP
M/s Ghani Brothers, 1st Floor, Karimjee Building, Opp HBL Bank, North Napier Road, Karachi, **MAH & Manufacturer:** Daewon Pharm Co.,Ltd, 24 Jeyakgondan 1-gil Hyangnam-eup, Hwaseong-si, Gyeonggi-do, Republic of Korea	Freefol MCT 1% Injection 20ml Vial (Propofol 10mg/ml) Each vial contains: Propofol…….200mg	20ml vial x10's As per brand leader

During processing the matter, it is observed that above product discussed and approved in 282nd meeting of Registration Board the name of M/s Haji Medicine, Company, Rawalpindi as per following details: -

Product License Holder & Manufacturer	Name of Drug / Composition	Demanded Pack / MRP
Manufacturer: M/s Daewon Pharm. Co., Ltd., 24, Jeyakgongdan 1-gil, Hyangnam-eup, Hwaseong-si, Gyeonggi-do, Republic of Korea. **Marketing Authorization Holder:** M/s Daewon Pharm. Co., Ltd., 386 Cheonhodearo, Sungdong-gu, Seoul, Republic of Korea	Freefol-MCT 1% Injection solution for IV Injection/ Infusion (200mg/20ml) Each 1ml emulsion contains: Propofol…… 10mg (Each vial of 20ml contains 200mg of propofol)	5'sx20ml vial 1.3 Usd per Vial
Decision M-282: Approved with shelf life of 2 years and as per Policy for inspection of Manufacturer abroad.		

Case History:

M/s Haji Medicine Co., B-327, Iqbal Road Rawalpindi application dated 08-12-2016 for registration of FREEFOL-MCT 1% Injection considered and approved in 282nd meeting of Registration Board as per following details:

Importer & Manufacturer	Brand name & Composition
M/s Haji Medicine Co., B-327, Iqbal Road Rawalpindi Manufacturer: M/s Daewon Pharm. Co., Ltd., 24, Jeyakgongdan 1-gil, Hyangnam-eup, Hwaseong-si, Gyeonggi-do, Republic of Korea. Market Authorization Holder:	FREEFOL-MCT 1% Injection solution for IV injection/infusion (200mg/20ml) Each 1ml emulsion contains: Propofol…… 10mg

M/s Daewon Pharm. Co., Ltd., 386 Cheonhodearo, Sungdong-gu, Seoul, Republic of Korea	

As per policy for inspection of manufacturer abroad inspection panel was constituted and letter issued dated 12-06-2019.

A letter dated 27-08-2019 received from M/s Haji Medicine Co., B-327, Iqbal Road Rawalpindi which is reproduced as under:

> *we have applied for registration and inspection of our Foreign principal of our Drug i.e. Inj. Freefol-MCT 1% 200mg/20ml (Propofol), manufactured by M/s Daewon Pharma Co. Ltd, Korea. In this regard, your office has constituted a two member panel for the inspection of Foreign Principals in Korea through Your letter No. F.8-2/2019-I&V-I dated 12-06-2019.*
> *The said panel was constituted to inspect manufacturing facilities of foreign principals of two other importers along with the manufacturing facility of our foreign principal.*
> *Now one of the importer i.e. M/s LA-Vie Pvt Ltd, Lahore has withdrawn his application and hence we only two importers are left to share the expenses related to visit of your panel to Korea.*
> *As it will be great burden to share all expenses by only two of us so it is requested of you that kindly add at least one other applicant to be inspected in Korea to our case so we may share expenses of this visit.*

Even lapse of years, you did not comply letter dated 27.08.2019 to carry out inspection. Furthermore, letter of authorization issued by M/s Daewon Pharm Co. Ltd, Korea was **valid till: 19, Feb, 2021.**

M/s Ghani Brothers, Karachi on dated 31-08-2022 also applied for registration of *"Freefol MCT 1% Injection 20ml Vial (Propofol 10mg/ml)"*, the Registration Board considered and approved the said product in **330th meeting of Registration Board from same manufacturer.** M/s Ghani Brothers, Karachi has submitted Sole Agency Agreement issued by *M/s Daewon Pharm Co. Ltd, Korea*. The letter stated that the manufacturer appoints M/s Ghani Brothers to register their products in Pakistan. The authorization letter is valid till 19-03-2026.

M/s Daewon Pharm Co. Ltd, Korea through DHL forward letter of **termination in the name of M/s Haji Medicine** Co., Rawalpindi.

In view of above, a Show Cause Notice issued to M/s Haji Medicine, Company, Rawalpindi on 11th January, 2024 and a reminder on 22nd January, 2024. In response firm has submitted their reply as under: -

> *"Please refer to your show cause letter for clarification regarding current status of Sole Distribution Agreement of imported drug i.e. Inj. Freefol-MCT 1% 200mg/20ml (Propofol) approved in our name form Product License Holder i.e. M/s Daewon Pharma Co. Ltd, Korea.*
>
> *This drug is approved in our name in 282nd meeting of Registration Board held on 14th – 15th May, 2018. The product was initially approved with the condition of inspection of manufacturer abroad and panel was formed to inspect 03 cases from Korea. As one of applicant withdrew his case so we requested you to add at least one more case so expense is reduced.*
>
> *In the meantime DRAP waived off requirement of inspection of PIC/s member countries including Korea. Hence registration letter should have been issued to us as per approval in 282nd meeting of registration Board held on 14th – 15th may, 2018.*
>
> *Please note that our letter of Authorization from M/s Daewon Pharma Co. Ltd Korea remained valid at the time of approval of registration.*
>
> *As the product is already approved in our name hence please issue registration letter in our name. we have already requested you through our letter No. HMC/23/244 dated 04-12-2023.*
>
> ***We are also in negotiation with M/s Daewon Pharma Co. Ltd, Korea. Hence please adjourn any further proceedings on this show cause until we received any feedback from M/s Daewon Pharma Co. Ltd, Korea".***

Decision:

The Registration Board deliberated on the matter in detail including the reply of the firm and decided as follow:

i. Approved the FREEFOL-MCT 1% Injection under the name of M/s Ghani Brothers, Karachi, based on valid market authorization and a Certificate of Pharmaceutical Product (CoPP) from the product license holder abroad.

ii. Cancelled the approval under the name of M/s Haji Medicine Co., Rawalpindi, due to termination of the agreement from the product license holder abroad.

Item No. III. Division of Biological Evaluation & Research

Sr. No.	Deputy Director	Designated No.	No. of Cases
1.	Mr. Muhammad Kashif	DD-I	13
2.	Ms. Haleema Shareef	DD-II	10
3.	Ms. Anam Saeed	DD-III	16
Total			**39**

CASES OF DD-I (MR. MUHAMMAD KASHIF)

Case. No.1 Extension in labelling exemption for Cerezyme (Reg. No. 107918)

M/s Sanofi Aventis Pakistan Limited, Karachi submitted that Cerezyme is indicated for a rare disease called Gaucher disease and required to be imported in a limited quantity. Therefore, it is not possible for manufacturer to follow the Packaging and labeling rules of every country at the time of export plus production, packaging, quality controls of this sterile and temperature sensitive product requires specialized methods and techniques of handling under highly controlled environment. The firm states that the last request of the firm for exemption of labeling text for Cerezyme (Reg. No. 107918) was approved by Registration Board in its 329th meeting for one year from the date of expiry of previous permission i.e., 22-05-2023. The firm requested to extend the exemption of Urdu Text, Registration number and MRP on packs of Cerezyme for a period of longer than one year. The firm has submitted import and sales record of the stated product as per following details:

Brand name Composition & Reg. No.	No. of unit packs imported			No. of unit packs sold		
Cerezyme						
Powder for concentrate for solution for infusion.	2021	2022	2023	2021	2022	2023
Each unit dose contains: Imiglucerase ….400U Reg. No. 107918	50	90	50	--	106	20

6 packs used for QI sampling.

The firm has submitted the following documents:

i. Fee Challan of Rs. 7500/- via e-deposit slip No. **8791309884** and differential fee of Rs. 2500/- via e-deposit slip No. **7689252265** dated **26- 03-2024**.
ii. Copy of local SOP for control of Over stamping Operations.
iii. An undertaking that to print the Registration Number and Maximum Retail Price (MRP) on each pack of above product at their Karachi site bearing DML No. 000007, before releasing the goods into the market.
iv. Copy of Registration letter dated 24-05-2021.
v. Copy of Valid DML & DSL
vi. Copy of permission of Extension in labeling exemption for Cerezyme (Reg. No. 107918) vide letter No. F.3-5/2014-DDC(BD)(V-VII) dated 04th December 2023.

Decision: Registration Board acceded the request of the firm and granted the permission, for two years from the date of expiry of previous permission i.e., 22-05-2024, to import Cerezyme 400U (l's, 5's & 25's) {Reg. No.107918) in Standard Export Packs and to locally print MRP and registration number along with Urdu Text, Registration number and MRP, before sale of Cerezyme 400U (l's, 5's & 25's) {Reg. No.107918), at M/s Sanofi Aventis, Plot 23, sector 22, Korangi Industrial Area, Karachi to comply with the requirements of Drugs (Labelling & Packing) Rules, 1986.

Case. No.2 One-time labelling exemption for Diclair-ST (Reg. No.059023)

M/s Gene-Tech Laboratories, Karachi has applied for one-time labeling exemption /relaxation of labeling for their already registered biological product Diclair-ST (Reg. No. 059023). The firm states that due to factory maintenance their next order of 20,000 units has been delayed till July 20, 2024, currently they have limited stock enough to cover till end of March, 20, 2024. To avoid any foresee shortage of this life saving medicine,

manufacturer has offered them below mentioned quantities with short shelf life, this has been packed & manufactured for other country by the manufacturer as per following details.:

Brand name Composition & Reg. No.	Manufacturer & Product License Holder (PLH)	Parameters
Diclair-ST 1,500,000 IU Injection Each Vial contains: Streptokinase….1,500,000 IU Reg. No. 059023	**Manufacturer:** M/s BBT Biotech GmbH, Arnold-Sommerfeld-ring, Baesweilder, Germany. **PLH**. Phare-Belgium, S.A, Schelle, Belgium	Quantities = 2968 vials Batch No. P03893 Mfg. Date: 1-1-2023 Exp Date: 31-12-2025

The firm has submitted the following documents:

I. Fee Challan of Rs. 7500/- via e-deposit slip No. **896327894692** and differential fee of Rs. 2500/- via e-deposit slip No. **710275655.**
II. Undertaking.
III. Copy of Registration letter.
IV. Copy of Valid DML & DSL.

Remarks of Evaluator:

1. Labeling details to be relaxed is not mentioned.
2. Agreement with a DML Holder where local printing as per drug labeling and packing rules will be done is not submitted.

Decision: Registration Board decided to grant one-time approval of printing of the Urdu Version, Registration number and MRP for 2968 vials (batch number P03893) of its already registered imported biological product Diclair-ST (Reg. No. 059023). The permission letter will be issued after the submission of the undertaking for the printing of only Urdu Version, Registration number and MRP and the Agreement of the importer with a local DML Holder where local printing as per the Drugs (labeling and packing) Rules, 1986 will be done.

Case.No.3 LIST OF REGISTERED (EUA) COVID-19 VACCINES WITH DRAP.

In 332nd meeting of Registration Board, it was advised to Biological Division to prepare a list of all those products which were granted EUA during COVID and place the same before the Board for further directions to MA Holders to submit complete data of the EUA products, as per international practices.

EUA COVID-19 vaccines with DRAP, is tabulated as follows:

Sr. No	Reg. No.	Brand Name	Importer Name	Manufacturer Name	Dosage-Pack	EUA Date
1	107879	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	National Institute of Health (NIH), Islamabad	M/s Beijing Institute of Biological Products Co., Ltd., No.6 & 9, Boxing 2"d Road, Economic-Technological Development Area, Beijing, 100176, China.	PFS	20-Jan-2021
2	107880	CoviShield ChAdOxl nCoV-19 Corona Virus Vaccine	Sindh Medical Store, Karachi	M/s Serum Institute of India Pvt. Ltd. 212/2, Off. Soli Poonawalla Road Hadapsar Pune, Maharashtra, India - 4l 1 028.	Vial	20-Jan-2021

3	107881	Gam-COVID-Vac Solution for Intramuscular Injection	AGP Limited, Karachi	Medgamal Branch, FSBI N.F. Gamaleya "National Research Center for Epidemiology and Microbiology" of the Ministry of Health of the Russian Federation, 18 Gamalei Street, Moscow 123098, Russia.	Vial (0.5mL)	1-Feb-2021
4	107885	Convidecia Vaccine in Prefilled Syringe	AJM Pharma (Pvt) Ltd, Karachi	M/s CanSino Biologics Inc., Floor 3 and 4, 185 South Ave., TEDA West District, Tianjin, China.	PFS	16-Feb-2021
5	107886	Convidecia Vaccine in Vial	AJM Pharma (Pvt) Ltd, Karachi	M/s CanSino Biologics Inc., Floor 3 and 4, 185 South Ave., TEDA West District, Tianjin, China.	Vial	16-Feb-2021
12	107927	Convidecia Vaccine	AJM Pharma (Pvt) Ltd, Karachi	M/s CanSino Biologics Inc., Floor 3 and 4, 185 South Ave., TEDA West District, Tianjin, China.	1's Vial (3 doses)	7-Mar-2021
13	107928	Convidecia Vaccine	AJM Pharma (Pvt) Ltd, Karachi	M/s CanSino Biologics Inc., Floor 3 and 4, 185 South Ave., TEDA West District, Tianjin, China.	1's Vial (10 doses)	7-Mar-2021
6	107887	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	National Institute of Health (NIH), Islamabad	M/s Beijing Institute of Biological Products Co., Ltd., No.6 & 9, Boxing 2"d Road, Economic-Technological Development Area, Beijing, 100176, China.	Vial	12-Mar-2021
7	107888	Gam-COVID-Vac Solution for Intramuscular Injection	AGP Limited, Karachi	M/s Generium Joint-Stock Company (Generium JSC), 601125, Vladimir Oblast, petushky District, Volginsky, ul. Zavodskaya, bld. 263, Russia.	Vial (3mL)	12-Mar-2021
8	107889	Gam-COVID-Vac Solution for Intramuscular Injection	AGP Limited, Karachi	M/s Closed Joint Stock Company "Pharmaceutical Company" LEKKO, 601125, Vladimir Oblast, Petushky District, Volginsky, ul. Zavodskaya, bld 277,279, Russia.	Vial (3mL)	12-Mar-2021

9	107890	Gam-COVID-Vac Solution for Intramuscular Injection	AGP Limited, Karachi	M/s Open Joint Stock Company Pharmastandard-UfaVlTA plant, Republic of Bashkortastan, Ufa, ul. Khudaiberdina, 28, Russia.	Vial (3mL)	12-Mar-2021
10	107891	Gam-COVID-Vac Solution for Intramuscular Injection	AGP Limited, Karachi	M/s Open Joint Stock Company Pharmastandard-UfaVlTA plant, Republic of Bashkortastan, Ufa, ul. Khudaiberdina, 28, Russia.	Ampoule (0.5mL)	12-Mar-2021
11	107897	CoronaVac Covid-19 Vaccine (Vero Cell), Inactivated	Varitron, Lahore	M/s **Sinovac** Lifesciences (Beijing Kexing Zhongwei Biotechnology) Co. Ltd., China	Vial	8-Apr-2021
14	107929	Gam-COVID-Vac Solution for Intramuscular Injection	MedAsk Distributor, Rawalpindi	M/s CJSC BIOCAD, 198515, St. Petersburg, Strelna, ul. Svyazi, 38, bld. 1, Russia.	Vial (0.5 mL)	7-May-2021
15	107930	Gam-COVID-Vac Solution for Intramuscular Injection	MedAsk Distributor, Rawalpindi	M/s Generium Joint-Stock Company (Generium JSC), 601125, Vladimir Oblast, petushky District, Volginsky, ul. Zavodskaya, bld. 263, Russia.	Vial (3mL)	7-May-2021
16	107931	CoronaVac Covid-19 Vaccine (Vero Cell), Inactivated	Varitron, Lahore	M/s **Sinovac** Lifesciences (Beijing Kexing Zhongwei Biotechnology) Co. Ltd., China	1's Vial (2 doses)	7-May-2021
17	107932	Comirnaty Concentrate for dispersion for injection	Pfizer Pakistan Limited, Karachi	M/s Pfizer Manufacturing Belgium NV, Belgium	6 doses/ vial	4-Jun-2021
18	107964	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	National Institute of Health (NIH), Islamabad	M/s Beijing Institute of Biological Products Co., Ltd., No.6 & 9, Boxing 2"d Road, Economic-Technological Development Area, Beijing, 100176, China.	Vial (5 doses)	20-Aug-2021

Decision: Registration Board keeping in view the International practices (RRA countries) has decided to direct all the EUA holders of above mentioned products to submit application on Form-5F along with approval of the product in the country of origin for consideration of Registration Board within six months' time.

The board further advised the division of BE&R to recheck the record as if any product remaining having EUA to be addressed in the same manner.

Case No. 4. Case of 331st Registration Board

Product Clotless Injection 40 mg Reg No 074149 and Clotless Injection 60mg, Reg No 074150. (Enoxaparin Sodium) of M/s Himont Pharmaceuticals Lahore for issuance show cause Notice for manufacturing the products without biological section.

M/s Himont Pharmaceuticals Lahore has applied for the release of their imported raw material Enoxaparin Sodium 0.925 Kg, B.No. 8ZE201001, Mfg.: Oct 6, 2020, Exp: Sep 2023 for their registered product Clotless Injection 40 mg Reg No 074149 and Clotless Injection 60mg, Reg No 074150. The remaining shelf life of the material is 35%.

Sr.No.	Brand Name and Registration No
1.	Clotless Injection 40 mg Reg No 074149
2.	Clotless Injection 60mg, Reg No 074150.

The case was placed in the 57th meeting of Committee for disposal of import cases of short shelf-life drugs. As Enoxaparin is a biological product hence the Licensing Division was asked to verify/confirm if the firm has approved biological section or not.

The licensing division has forwarded the last inspection report conducted for renewal of DML of the firm wherein it is evident that the firm do not have separate approved section for biological products. The case was processed to the Chairman RB to issue show cause to the firm and the case was returned to BE&R Division with advice to place the matter of registration of product **'Noclot"** before the forthcoming meeting of Registration Board please. As the Chairman is not authorized in such case for approval of issuance of show cause notice.

Decision of 323rd R.B Meeting:

"Registration board advised to issue a show cause notice to M/s Himont Pharmaceuticals Lahore to explain as to why not the registrations Clotless Injection 40mg Reg. No.074149 and Clotless Injection 60mg, Reg. No.074150 cancelled as the biological section for production of biological drugs is not available. The Board further advised to ask the firm that if they desire to be heard in person they may inform accordingly.**"**

In light of above, show cause notice was issued to the firm vide No.3-174/2018-ADC(BD)(Vol-I) dated 31st March 2023 in which it was stated that the firm will submit their reply within 15 days. If they want to be heard in person before the Registration Board, they may intimate the same.
The firm did not reply; however, the firm had already explained the matter vide letter No. HP-BIO-004 dated 21st November 2022. Wherein they stated that they have constructed separated biological section and letter has been submitted for Panel constitution in DRAP office Lahore, for inspection of new ready, liquid biological section vide letter No. HP-BIO-003 dated 05th October 2022.

Decision of 331st Registration Board:

"Registration board advised to issue a show cause notice to M/s Himont Pharmaceuticals Lahore to explain as to why not the registrations Clotless Injection 40mg Reg. No.074149 and Clotless Injection 60mg, Reg. No.074150 may be cancelled as the biological section for production of Biological drugs is not available."

In view of above M/s Himont Pharmaceuticals (Pvt.) Ltd was again issued a show cause notice vide letter No. 3-174/2018-AD(BD)(Vol-I) dated 23rd February 2024 for which they have submitted the reply No. HP-BIO-006-27th February 2024 wherein they have stated that their section has been visited by the panel, but no approval letter has been issued by the Licensing Division till yet.
A letter has been issued to the firm for personal hearing.

Proceeding in the Meeting:

The firm appeared through its representative M. Kashif Latif who submitted the authority letter on company letter Head and stated that the registration was issued when the biological section was not required for registration of the products Clotless Injection 40mg Reg. No.074149 and Clotless Injection 60mg, Reg.

No.074150, and they have only manufactured the said products during the COVID pandemic on campaign basis on the directions contained in the letter No.CDC/P&S/SL-28/2021 and letter No.CDC/4-1/2021 dated 06-05-2021 received to them from Chief Drugs Controller Punjab from Primary and secondary Healthcare Department Punjab.

During the hearing, M. Kashif Latif appraised the Board that a panel constituted by the licensing division inspected the Biological section and inspection report has been submitted by the firm in reply to their show cause notice to BE&R, Division wherein the panel has recommended its Biological section.

M. Kashif Latif further informed the Board that their case is not placed in the CLB Meeting till yet and approval thereof is still awaited.

Decision: The Board in the light of the proceedings and after detailed deliberation decided to suspend the registration of Clotless Injection 40mg Reg. No.074149 and Clotless Injection 60mg, Reg. No.074150 till approval of Biological Section of M/s Himont Pharmaceuticals (Pvt.) Ltd. Lahore by the Central Licensing Board.

Case. No.5 <u>For information (Ratification) of the Registration Board.</u>

M/s. Eli Lilly Pakistan (Pvt) Limited, Karachi had applied for the change in manufacturing site of their following registered biological product and the same were presented by the BE&R Division in 332nd Registration Board Meeting and the Board approved their request as per following details:

Reg. No. and date	Brand Name	Decision of 332nd Registration Board Meeting
008302 Dated 24-09-1985	**Humulin R, 100IU/mL Vial** Each vial contains: Human insulin Regular (rDNA Origin)	**The Board was apprized that Special Investment and facilitation council, Prime Minister's Office vide letter No. F-5 (30) 09 / SIFC Islamabad dated 23rd November 2023 has also forwarded request of the company for support needed in the interest of diabetes patients. Keeping in view data / documents / information along with original legalized CoPP clearly indicating Marketing Authorization Holder as M/s Eli Lilly and Company Indianapolis, IN 46285, US, the Board acceded to request of the pharmaceutical concern for change of manufacturing site from M/s Eli Lilly and Company Indianapolis, IN 46285, USA to M/s. Gland Pharma Limited, Sy No. 143 to 148, 150 & 151, Near Gandimaisamma Cross Roads, D.P. Pally, Dundigal Post, Dundigal - Gandimaisamma Mandal, Medchal-Malkajgiri District, Hyderabad - 500 043, Telangana, INDIA for already registered products namely; Humulin R 100IU/ml vial, Humulin N 100IU/ml vial and Humulin 70/30 100IU/ml vial subject to submission of legalized GMP certificate issued by Korea Ministry of Food & Drug Safety and compliance to current import policy for finished drugs. Reference shall be sent to Cost & Pricing division for price confirmation.**
008300 Dated 24-09-1985	**Humulin N, 100IU/mL Vial** Each vial contains: Human insulin NPH Isophane Suspension (rDNA Origin)	
011149 Dated 28-07-1990	**Humulin 70/30, 100IU/mL Vial** Each vial contains: 70% human insulin isophane suspension, 30% human insulin (rDNA Origin)	

M/s Eli Lilly Pakistan (Pvt) Limited, Karachi had submitted application for inspection exemption of virtual GMP inspection abroad, which states that M/s. Gland Pharma Limited is approved by the Korea Ministry of Food and Drug Safety (MFDS) to Manufacture above products and Korea is the member of PIC/S. The firm has not submitted any CoPP or GMP issued by the MFDS Korea but the firm M/s. Eli Lilly Pakistan (Pvt) Limited, has submitted an application for exemption of inspection abroad and provided link for verification that M/s Gland

Pharma is on the official website of the Food and Drug Safety (MFDS) Korea, and the same has been verified online that M/s Gland Pharma is on the official website of the Food and Drug Safety (MFDS) Korea.

The firm has also provided the following link which it can be checked and verified that M/s Gland Pharma Limited is on the official website of Korea Ministry of Food and Drug Safety (MFDS).
https://nedrug.mfds.go.kr/pbp/CCBEM01/getList?totalPages=1061&page=1&limit=10&sort=&sortOrder=&searchYn=true&entpName=%ED%95%9C%EA%B5%AD%EB%A6%B4%EB%A6%AC&mnfctrName=&mnfctrCountryCode=&btnSearch=

The request of the firm for inspection exemption of virtual GMP inspection abroad was acceded to by the Chairman Registration Board, and the letter for the above stated change was issued accordingly by the division of BE&R. The Chairman Registration Board also advised to place the case in the coming meeting of registration board for ratification.

Decision: The Board endorsed the above stated information and Decision and also directed the firm to make sure the consistent availability of Human Insulin.

CASES OF DD-II (MS. HALEEMA SHAREEF)

Evaluator: Ms. Haleema Sharif
Priority / Out of Queue consideration of Heparin, & Insulin
Molecule: Heparin Sodium

6.	**Name, address of Applicant / Importer**	M/s AJM Pharma (Pvt.) Ltd. 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan.
	Details of Drug Sale License of importer	License No: 262 Godown Address: Ground floor, Plot no. 44 Sector 27, Korangi Industrial Area, Karachi Validity: 22.02.2028 Status: License to sell drugs (Form-7)
	Name and address of marketing authorization holder (abroad)	M/s Shenzhen Techdow Pharmaceutical Co., Ltd. No. 19, Gaoxinzhongyi Road, Nanshan District, Shenzhen City, Guangdong Province 518057 People's Republic of China
	Name, address of manufacturer(s)	M/s Shenzhen Techdow Pharmaceutical Co., Ltd. No. 19, Gaoxinzhongyi Road, Nanshan District, Shenzhen City, Guangdong Province 518057 People's Republic of China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	**CoPP:** The firm has submitted original, legalized CoPP (57PK-SXMZ) issued by United State Food & Drug Administration 10903 New Hampshire Ave, Silver Spring, MD 20993, United State of America, the certificate confirm that the product is actually on the market in the exporting country and facilities and operations conform to EU-GMP as recommended by WHO. The certificate is valid till 27-10-2025.
	Details of letter of authorization / sole agency agreement	Copy of product specific sole agency agreement from manufacturer abroad authorizes M/s AJM Pharma (Pvt.) Ltd. Karachi as their exclusive agent to register and market our following product in the territory of Pakistan.

	Status of the applicant	☐Manufacturer ☒Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Tracking i.d # N8E-DMJ-YZED, Dated: 19.03.2024
	Details of fee submitted	Rs: 300,000/- Dated: 18.03.2024. Deposit Slip No. 8986718917
	The proposed proprietary name / brand name	Heparin Sodium Injection, USP 5,000 USP Units/ mL [10mL Multi Dose Vial]
	Strength / concentration of drug of ActivePharmaceutical ingredient (API) per unit	Each 10ml Vial contains: Heparin Sodium USP …… 5,000 Units/ mL (equivalent to Heparin).
	Dosage form of applied drug	Liquid Injection
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Finished product specifications	USP specifications
	Proposed Pack size	25's × 10 ml per vial
	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	Store at 20° to 25°C
	Reference Regulatory Authorities	Heparin Sodium Injection, USP 5,000 USP Units/mL (10mL Multi Dose Vial) USFDA Approved. Same Manufacturer: M/s Shenzhen Techdow Pharmaceutical Co., Ltd.
	For generic drugs (me-too status)	Brand name: HEPARIN-INDAR 5000 IU/ ml Market Authorization Holder Pakistan: Eastern Medical Care Pvt Ltd Manufacturer Abroad & Product License Holder: Private Joint-Stock Company, 5, Zroshuvalana Str., Kyiv, 02099, Ukraine

Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Name, address of drug substance manufacturer	M/s Shenzhen Hepalink Pharmaceutical Group Co., Ltd No. 1, Rongtian South, Kengzi Sub-district, Pingshan New District Shenzhen City, Guangdong Province 518122 People's Republic of 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	Firm has submitted stability study data of 3 batches at long term conditions at 25°C ± 2°C / 60% ± 5% R.H for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% R.H for 06 months for accelerated conditions.
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 the product	Firm has submitted the details of analytical method validation.
Container closure system of the drug product	Heparin Sodium Injection, 5000IU/mL Injection USP (10mL/Vial) will be marketed in the following Pack 10mL clear Type-I glass vials stoppered with grey rubber stopper and sealed with aluminum seals having Red PP disc.

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of Heparin Injection at accelerated and real time conditions. The real time stability data conducted at 25°C ± 2°C / 60% ± 5% R.H for 24 months and accelerated stability data conducted at 40°C ± 2°C / 75% ± 5% R.H for 06 months for 3 batches. CW00132A (Upright) CW00132A (Inverted) CW00142A (Upright) CW00142A (Inverted) CW00152A (Upright) CW00152A (Inverted)
	Remarks of Evaluator:	
	Decision: **Keeping in view the legalized COPP indicating product availability in the country of origin and approval status of product in USFDA, Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.**	
7.	Name, address of Applicant / Importer	**M/s. Atlantic Pharmaceuticals, C-1, D13, Sector 16, K.I.A, Karachi**
	Details of Drug Sale License of importer	License No: **597** Address: C-1, D13, Sector 16, K.I.A, Karachi. Validity: 24.02.2028
	Name and address of marketing authorization holder	**In Pakistan:** M/s. Atlantic Pharmaceuticals, C-1, D13, Sector 16, K.I.A, Karachi **In Egypt:** M/s. South Egypt Drug Industrial Co. (SEDICO) First Industrial Zone – 6 October City– Egypt
	Name, address of manufacturer(s)	**M/s. South Egypt Drug Industrial Co. (SEDICO)** First Industrial Zone – 6 October City– Egypt
	Name of exporting Country	Egypt
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has attached CoPP No. 01773/2021/H issued on 24th October 2021, subject to inspection after two years. Firm has attached **Free Sale Certificate** 00687/2021/H issued on 26-Sept-2021 September 2023, issued by Egyptian Drug Authority. Firm has attached GMP Certificate No. 196/2022 issued on 15th March2022, issued by Egyptian Drug Authority.
	Details of letter of authorization / sole agency agreement	Firm has attached sole Agency agreement No. 43/2021 signed by both the parties.
	Status of the applicant	☐Manufacturer ☒**Importer** ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒**Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☒**Domestic sale** ☐Export sale ☐Domestic and Export sales

	For imported products, specify one the these	☒**Finished Pharmaceutical product import** ☐Bulk import and local repackaging ☐Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	CTD Dossier Dy. No; 26881R&I Dated: **29th Sept. 2021**
	Details of fee submitted	Rs: 150,000/- Dated: 13-08-2021 (Slip No. 3722531524)
	The proposed proprietary name / brand name	Insulin H Bio R 100
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Recombinant Human Insulin 100IU/1ml
	Dosage form of applied. Drug	Injectable Presentation: Vial
	Pharma co therapeutic Group of (API	Anti-Diabetic Insulin analogues
	Reference to Finished product specifications	Ph. Eur. Specifications
	Proposed unit price	As per DPC
	Shelf Life	30 Months
	Storage Conditions	- Store at 2 °C to 8 °C - Avoid freezing - Keep medicine out of reach of children
	The status in reference regulatory authorities	Humulin® R for injection in vial Eli Lilly and Company Limited, Indianapolis, USA
	For generic drugs (me-too status)	Humulin® R for injection in vial Eli Lilly and Company Limited, Indianapolis, USA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. 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. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and validation, 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
	Name, address of drug substance manufacturer	Biocon Limited: 20th KM. Hosur Road, Electronics City, Bangalore - 560 100, INDIA Wockhardt Limited H-14/2, M.I.D.C Area, Waluj, Aurangabad – 431 136, INDIA.
	Module-III Drug Substance:	Firm has submitted details drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, 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 that Six month accelerated(5±3ºC) and 48-month long term (-20±3ºC) stability studies of batch No., IA37055/I, IA37056/I, IA37057/I, was conducted by firm. However, firm has not submitted reports.
	Module-III Drug Product:	Firm has submitted details drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Analytical method validation of Product	Firm has submitted analytical method validation report of insulin injection Assay.
	Container closure system of the drug product	Insulin H Bio R 100 IU Vial is packed in glass vial type I & rubber stopper which have. excellent resistance to water, moisture and most organic solvents and chemicals also it is fairly good oxygen barrier and have a great stiffness.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of1 batches. The real time stability study data is conducted at 05°C ± 3°C for 30 months.
	Module-IV Non-Clinical	Not submitted
	Module-V Clinical	Not submitted
	Remarks of Evaluator	• Bio similarity data as per WHO guideline is required (including analytical studies; Physicochemical Biological and Clinical studies; immunogenicity studies, Pk, Studies). • Stability studies data of three batches of Drug product at 0,3,6,9,12,18, 24 months is required as firm has submitted stability data of only one batch at 0, 6, 12, 18, 24, 30months. • Stability studies reports of three batches of Drug substance is required.
	Decision: Registration Board deferred the case for provision of following: • **Structural comparison with Innovator product as per Guidelines.** • **At least one repeat dose toxicity study as part of Non-Clinical study.** • **Stability study data at 3 and 9 months OR Scientific Rationale of skipping 3rd & 9th month time points.** • **Stability study report of 3 Drug Substance batches.**	
8.	Name, address of Applicant / Importer	**M/s. Atlantic Pharmaceuticals, C-1, D13, Sector 16, K.I.A, Karachi.**
	Details of Drug Sale License of importer	License No: **597** Address: C-1, D13, Sector 16, K.I.A, Khi. Validity: 24.02.2023
	Name and address of marketing authorization holder	In Pakistan: **M/s. Atlantic Pharmaceuticals, C-1, D13, Sector 16, K.I.A, Karachi** In Egypt: **M/s. South Egypt Drug Industrial Co. (SEDICO) First Industrial Zone – 6 October City– Egypt**
	Name, address of manufacturer(s)	**M/s. South Egypt Drug Industrial Co. (SEDICO)** First Industrial Zone – 6 October City– Egypt

	Name of exporting Country	**Egypt**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has attached CoPP No. 01774/2021/H issued on 24th October 2021, subject to inspection after two years. Firm has attached **Free Sale Certificate** 00494/2023/H issued on 04th September 2023, issued by Egyptian Drug Authority. Firm has attached GMP Certificate No. 196/2022 issued on 15th March2022, issued by Egyptian Drug Authority.
	Details of letter of authorization / sole agency agreement	Firm has attached sole Agency agreement No. 43/2021 signed by both the parties.
	Status of the applicant	☐Manufacturer ☒**Importer** ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒**Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☒**Domestic sale** ☐Export sale ☐Domestic and Export sales
	For imported products, specify one the these	☒**Finished Pharmaceutical product import** ☐Bulk import and local repackaging ☐Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	CTD Dossier Dated: **30th Sept. 2021**
	Details of fee submitted	Dy. No; 30 September2021 Rs: 150,000/- Dated: 13-08-2021 (Slip No. 707051580)
	The proposed proprietary name / brand name	Insulin H Mix 100
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Human Insulin…….30IU/ml Isophane Human insulin……70IU/ml
	Dosage form of applied. Drug	Injectable Presentation: Vial
	Pharma co therapeutic Group of (API	Anti-Diabetic Insulin analogues
	Reference to Finished product specifications	Ph. Eur. Specifications
	Proposed unit price	As per DPC
	Shelf Life	30 Months
	Storage Conditions	- Store at 2 °C to 8 °C - Avoid freezing - Keep medicine out of reach of children
	The status in reference regulatory authorities	**Humulin® 70/30 suspension for injection in vial** Eli Lilly and Company Limited, Indianapolis, USA
	For generic drugs (me-too status)	**Humulin® 70/30 suspension for injection in vial** Eli Lilly and Company Limited, Indianapolis, USA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. 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. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and validation, 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
	Name, address of drug substance manufacturer	1. Biocon Limited: 20th KM. Hosur Road, Electronics City, Bangalore - 560 100, INDIA 2. Wockhardt Limited H-14/2, M.I.D.C Area, Waluj, Aurangabad – 431 136, INDIA.
	Module-III Drug Substance:	Firm has submitted details drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, 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)	Not submitted
	Module-III Drug Product:	Firm has submitted details of drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Analytical method validation of Product	Firm has submitted analytical method validation report of insulin injection Assay.
	Container closure system of the drug product	Insulin H Mix 100 IU Vial is packed in glass vial type I & rubber stopper which have excellent resistance to water, moisture and most organic solvents and chemicals also it is fairly good oxygen barrier and have a great stiffness.
	Stability study data of drug product, shelf life and storage conditions	The firm has submitted accelerated (25°C ± 3°C, 60%RH± 5) real time stability study (05°C ± 3°C) data of two batches at for 30 months at 0, 6, 12, 18, 24, 30month time intervals.
	Bio Similarity Studies	Firm has submitted bio similarity studies with following details, Test Product: Insulin H Mix Reference Product: Mixtard 30 HM by Novo Nordisk Study Centre: Pharmaceutical Service Center, College of Pharmacy, University of Tanta, Egypt. Analytical method: A photometric assay method for the determination of glucose concentration in whole blood. **Methodology:** Eligible subjects received test and reference preparation as a single subcutaneous injection on two different occasions, five days apart. Blood samples were collected before and at **15, 30, 45, 60, 90, 120, 150, 180, 210** and **240 minutes** after administration. Analysis of blood glucose concentrations in each sample by means of a photometric assay method was performed. Statistical comparisons of both preparations were based on the target therapeutic effect.

		Conclusion: The test drug product **Insulin H Mix 100 IU suspension** (30/70 mixture Human Insulin & Protamine Insulin Human) manufactured by SEDICO Pharmaceutical Co., 6 October City, Egypt, is bio similar to the reference brand **Mixtard 30 HM suspension** (Biphasic Isophane Insulin injection 30/70) manufactured by Novo Nordisk A/S, 2880 Bagsvaerd, Denmark.
	Module-IV Non-Clinical	N/A
	Module-V Clinical	N/A
	Remarks of Evaluator	• Bio similarity data as per WHO guideline is required (including analytical studies; Physicochemical Biological and Clinical studies; immunogenicity studies, Pk, PD studies). • Stability studies data of 1 batch of Drug product at 0,3,6,9,12,18, 24 months is required. • Clarification/Justification for submission of real time stability studies data at 0, 6, 12, 18, 24, 30 months' time intervals or evidence of guideline supporting this time interval. • Stability studies data of three batches of Drug substance is required.
	Decision: Registration Board deferred the case for provision of following: • **Structural comparison with Innovator product as per Guidelines.** • **At least one repeat dose toxicity study as part of Non-Clinical study.** • **Stability study data at 3 and 9 months OR Scientific Rationale of skipping 3rd & 9th month time points.** • **Stability study report of 3 Drug Substance batches.**	
9.	Name, address of Applicant / Importer	**M/s. Atlantic Pharmaceuticals, C-1, D13, Sector 16, K.I.A, Karachi.**
	Details of Drug Sale License of importer	License No: **597** Address: C-1, D13, Sector 16, K.I.A, Karachi. Validity: 24.02.2023
	Name and address of marketing authorization holder	In Pakistan: **M/s. Atlantic Pharmaceuticals, C-1, D13, Sector 16, K.I.A, Karachi** In Egypt: **South Egypt Drug Industrial Co. (SEDICO)** First Industrial Zone – 6 October City– Egypt
	Name, address of manufacturer(s)	**South Egypt Drug Industrial Co. (SEDICO)** First Industrial Zone – 6 October City– Egypt
	Name of exporting Country	**Egypt**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has attached CoPP No. 01823/2021/H issued on 24th October 2021, subject to inspection after two years. Firm has attached **Free Sale Certificate** 00761/2021/H issued on 12-Oct-2021, issued by Egyptian Drug Authority. Firm has attached GMP Certificate No. 196/2022 issued on 15th March2022, issued by Egyptian Drug Authority.
	Details of letter of authorization / sole agency agreement	Firm has attached sole Agency agreement No. 43/2021 signed by both the parties.
	Status of the applicant	☐Manufacturer

		☒**Importer** ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒**Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☒**Domestic sale** ☐Export sale ☐Domestic and Export sales
	For imported products, specify one the these	☒**Finished Pharmaceutical product import** ☐Bulk import and local repackaging ☐Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	CTD Dossier Dated: **04th Nov. 2021**
	Details of fee submitted	Dy. No; N/A Rs: 150,000/- Dated: 13-08-2021 (Slip No. 04743111876)
	The proposed proprietary name / brand name	**Insulin H Bio NPH**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains, Recombinant Human Insulin 100IU/ml Protamine sulfate……0.24IU/ml Or Each ml contains, Insulin isophane……100 IU *The Quantity of protamine sulphate varies according to assay of recombinant human insulin and its isophane ratio.
	Dosage form of applied. Drug	Injectable Presentation: Vial
	Pharma co therapeutic Group of (API	Anti-Diabetic Insulin analogues
	Reference to Finished product specifications	Ph. Eur. Specifications
	Proposed unit price	As per DPC
	Shelf Life	30 Months
	Storage Conditions	- Store at 2 °C to 8 °C - Avoid freezing - Keep medicine out of reach of children
	The status in reference regulatory authorities	**Humulin® N 100 IU/ml suspension for injection** Eli Lilly and Company Limited, Indianapolis, USA
	For generic drugs (me-too status)	**Humulin® N 100 IU/ml suspension for injection** Eli Lilly and Company Limited, Indianapolis, USA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. 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. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and validation, 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
	Name, address of drug substance manufacturer	1. Biocon Limited: 20th KM. Hosur Road, Electronics City, Bangalore - 560 100, INDIA 2. Wockhardt Limited H-14/2, M.I.D.C Area, Waluj, Aurangabad – 431 136, INDIA.
	Module-III Drug Substance:	Firm has submitted details drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, 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)	Not provided
	Module-III Drug Product:	Firm has submitted details drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Analytical method validation of Product	Firm has submitted analytical method validation report of insulin injection Assay.
	Container closure system of the drug product	Insulin H Bio NPH 100 IU Vial is packed in glass vial type I & rubber stopper which have excellent resistance to water, moisture and most organic solvents and chemicals also it is fairly good oxygen barrier and have a great stiffness.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The real time stability study data is conducted at 05°C ± 3°C for 30 months.
	Bio Similarity Studies	Firm has submitted bio similarity studies with following details, Test Product: Insulin H^{Bio} NPH Reference product: Insulatard HM by Novo Nordisk Study Centre: Pharmaceutical Service Center, College of Pharmacy, University of Tanta, Egypt. **Analytical Methods:** A photometric assay method for the determination of glucose concentration in whole blood. **Methodology** Eligible subjects came on three different occasions, one week apart. On the first occasion: they didn't receive any insulin preparation. On the other two different occasions: they receive test and reference preparations as a single subcutaneous injection. Blood samples were collected before and at **1, 2, 3, 4, 5, 6** and **7 hours** after administration. Analysis of blood glucose concentrations in each sample by means of a photometric assay method was performed. Statistical comparisons of both preparations were based on the target therapeutic effect. **Conclusion:** The test drug product **Insulin H^{Bio} NPH 100 IU suspension** (recombinant human insulin with protamine sulphate) manufactured by SEDICO Pharmaceutical Co., 6 October City, Egypt, is

		bioequivalent to the reference brand **Insulatard® HM suspension** (Insulin human, biosynthetic suspension for injection) manufactured by Novo Nordisk A/S, 2880 Bagsvaerd, Denmark.
	Module-IV Non-Clinical	Not provided
	Module-V Clinical	Not provided
	Remarks of Evaluator	• Bio similarity data as per WHO guideline is required (including analytical studies; Physicochemical Biological and Clinical studies; immunogenicity studies, Pk, PD studies). • Stability studies data of three batches of Drug substance is required.
	Decision: Registration Board deferred the case for provision of following: • **Structural comparison with Innovator product as per Guidelines.** • **Stability study report of 3 Drug Substance batches.**	

Cases of M/s. Ottoman Pharma deferred in 296th Meeting of Registration Board.

Sr. No.	**Name and address of product manufacturer (Applicant)**	**M/s Ottoman Pharma** 10 km, Raiwind Road, Lahore.
10.	Brand Name +Dosage Form + Strength	OTTO FLU VAC A/B Injectable Emulsion Avian Influenza Viruses (AIVs) H7 & H9
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No.11554 & 6614 Date:05-03-2019 & 20-05-2019 Rs. 20,000/- Date: 05-03-2019
	Composition	Each dose contains: Inactivated AIV H7N3[Not less than $EID_{50}10^9$/ml…..0.075ml Inactivated AIV H9N2[Not less than $EID_{50}10^9$/ml…..0.075ml
	Pharmacological Group	Veterinary vaccine
	Finished Product Specification	As per Innovators spec.
	Shelf Life	12 Months (2-8^{0}C)
	Document Details	i. Copy of DML No. 000502, Date of issue 05-08-2017 ii. Fee Challan Rs. 20,000/- iii. Panel inspection for renewal of DML dated 19-12-2017 wherein the panel rated the facility good and recommended the renewal.
	Pack size & Demanded Price	300ml/vial **Decontrolled**
	Products already registered in Pakistan	Not Available as per record
	Remarks of Evaluator (M. Zubair Masood)	

Decision in 296th Registration Board meeting:

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

a. Scientific justification of use of H7N3 and H9N2 in single product.
b. Notarized copy of valid GMP certificate.
c. Application on Form-5D being new product.
d. Differential fee of Rs. 30,000/-

Evaluation by DBE&R:

Firm has submitted following:

i. Ottoman Pharma is already manufacturing its Registered product "**OTTO FLU VAC**" **Reg. No. 028580**, that is oil-based vaccine containing AIV H7 and AIV H9, we just need the same product in aqueous base.
ii. There should not be any further requirement of scientific justification for both viruses used in a single product for said registration **of OTTO FLU VAC A/B** (aqueous based).
iii. Many products of Ottoman Pharma containing more than one virus in aqueous base are already registered.
    a. OTTO HPS VAC

b. OTTO NDFLU VAC A/B
c. OTTO H9 VAC A/B

iv. Grand Pharma (Pvt) Ltd. Is also manufacturing the same formulation under the brand name of **GPVAC FLU 7+9**

v. Sindh Poultry Vaccine Centre is also marketing the same formulation under the name "**Al-Plain (H7, H9)**" in aqueous base form.

vi. Notarized copy of valid GMP is submitted by firm.

vii. Application on Form 5D is not required as the formulation is not new.

Decision:
Registration Board keeping in view response of the firm and on recommendation of Veterinary Expert Member Registration Board approved the subject product.

11.	**Name and address of product manufacturer (Applicant)**	**M/s Ottoman Pharma** 10 km, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	OTTO ND+H5 Injectable Emulsion Avian Influenza Viruses (AIVs) H5 & New Castle Disease Virus
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No.11555 & 6614 Date:05-03-2019 & 20-05-2019 Rs. 20,000/- Date: 05-03-2019
	Composition	Each dose contains: Inactivated Newcastle Disease Virus containing EID_{50} not less than $10^{7.0}$/ml and HAU not less than 64…..0.06ml Inactivated AIV H9N2 containing EID_{50} not less than $10^{7.0}$/ml and HAU not less than 64…..0.06ml
	Pharmacological Group	Veterinary vaccine
	Finished Product Specification	As per Innovators spec.
	Shelf Life	12 Months (2-80C)
	Document Details	i. Copy of DML No. 000502, Date of issue 05-08-2017 ii. Fee Challan Rs. 20,000/- iii. Panel inspection for renewal of DML dated 19-12-2017 wherein. the panel rated the facility good and recommended the renewal.
	Pack size & Demanded Price	300ml/vial **Decontrolled**
	Products already registered in Pakistan	Not Available as per record.
	Remarks of Evaluator (M. Zubair Masood)	

Decision in 296th Registration Board meeting:
Registration Board deferred the case for submission of following by the firm:

a. Scientific justification of use of H7N3 and H9N2 in single product.
b. Notarized copy of valid GMP certificate.
c. Application on Form-5D being new product.
d. Differential fee of Rs. 30000/-

Evaluation by DBE&R:
Firm has submitted following:

Combination of AIV H5 and NDV is well established and duly supported by international research publication as under.

i. Lee DH, Park JK, Kwon JH, Yuk SS, Erdene-Ochir TO, Jang YH, Seong BL, Lee JB, Park SY, Choi IS, Song CS. **Efficacy of single dose of a bivalent vaccine containing inactivated Newcastle disease virus and reassortant highly pathogenic avian influenza H5N1 virus against lethal HPAI and NDV infection in chickens**. PLoS One. 2013;8(3): d58186. Doi:10.1371/journal.pone.0058186. Epub 2013 Mar 1. PMID: 23469269; PMCID:PMC3585801.

ii. A product named "**MEFLUVAC H5+ND**" is also being manufactured by a well-known American company "**Kemin**"

iii.	A product named as "**Medivac ND-AI**" containing AIV H5 and NDV is also being manufactured by a well-known Indonesian company "**Medion**".
iv.	Notarized copy of valid GMP is submitted by firm.
v.	Application on Form 5D is not justified as product is not new.
Decision: **Registration Board keeping in view response of the firm and on recommendation of Veterinary Expert Member Registration Board approved the subject product.**	

12. Request for change of Brand name of TALTZ Injection 80mg/ 1mL of M/s Eli Lilly Pakistan (Pvt) Ltd.

Following product of M/s Eli Lilly Pakistan (Pvt) Ltd, Karachi was approved in 297th meeting of Registration Board as per following details:

Molecule: Ixekizumab
Evaluator: Ms. Haleema Shareef

Sr. No.	Name of Manufacturer	Brand Name & Composition	Pack Size	Decision of RB in 297th Meeting
1	M/s Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285, USA	TALTZ Injection 80mg/ 1mL Each autoinjector prefilled pen contains: Ixekizumab: 80mg/mL Shelf Life: 24 months(5^0C)	1's Prefilled Pen (Autoinjector)/ As per SRO	Keeping in view valid legalized CoPP and approval of USFDA (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs

The product is not yet registered as Federal Government has not yet notified the price of above product. Now the firm has submitted the application for change in brand name as per following details:

Already Approved Brand Name	Newly Applied Brand Name
Taltz Injection 80mg/ 1mL	Aryzing Injection 80mg/1mL

The application of the firm is evaluated as per SOPs of 283rd meeting of Registration Board:

Sr.	SOPs approved in 283rd Meeting	Documents submitted by the firm
i.	Application with required fee as per relevant SRO (in case of similarity/ resemblance with drug, fee will note be required).	Submitted
ii.	Copy of registration letter and las renewal status.	Not Applicable
iii.	Justification for proposed change.	Submitted
iv.	Information regarding previous change of brand name since registration do drug.	Not Applicable
v.	Details (batch number, date of manufacture, quantity and stock position) regarding last batch imported.	Not Applicable
vi.	An undertaking that the proposed names do not resemble with already registered brands. In case of resemblance/ similarity with already change immediately. Moreover, no case is pending at any forum/ court of law regarding this matter.	Submitted
vii.	Original and legalized Certificate of Pharmaceutical Product as per WHO format for new brand name or Original and legalized GMP certificate of new brand name with free sale certificate from regulatory body of country of origin.	Submitted
viii.	Undertaking that the provided information/ documents are true/ correct.	Submitted

Registration Board in its 307th meeting authorized its Chairman for approval of change in brand name of registered drugs. Although the instant product is not yet registered, however is already approved by the Board for registration.

Therefore, the case was processed to Chairman Registration Board for perusal /approval of change in brand name from Taltz Injection to Aryzing Injection wherein he advised to process case after fixation of price. Now the firm requested to change brand name from Taltz to **Aryzing** for Pakistan before going in Pricing. This

is due to the Company's internal recommendation based on different brand name assigned to different countries for marketing and commercial reasons.

Decision in 334th Registration Board meeting:

Registration Board deferred the case for clarification from the firm whether it is innovator product or otherwise. The firm is required to submit its response with 07 days.

Response of firm.

Firm has Submitted following response:

We would like to confirm that **"lxekizumab"** is the Innovator Molecule of Eli Lilly and launched in US under the brand name **Taltz.** The same product we would like to register in Pakistan under the brand name **Aryzing.**

Firm has further quoted example of their product **"Verzenio"** which was approved in 297th RB meeting as an innovator product as recorded in meeting minutes.

We have another example of our anti -cancer product 'Verzenio' for which we changed the name to ' Yular eb' before going to pricing. Details are as follows:

- 297th DRB Meeting approved Verzenio as our Innovator product.
- We applied Brand Name Change from Verzenio to Yulareb before going to Pricing.
- DRAP considered our application on file and approved internally without taking it to DRB Meeting and communicated to Pricing Accordingly.
- Pricing issued SRO with new Name Yulareb instead of Verzenio.

Based on the above clarification, we request to kindly approve our change of brand name.

Decision: In the light of clarification provided by firm Registration Board approved the change of Brand name of subject product from "Taltz Injection 80mg/ 1mL" to "Aryzing Injection 80mg/1mL"

13. REGISTRATION OF IMPORTED HUMAN BIOLOGICAL FROM M/S MORGAN TECHNOLOGIES SERVICES, KARACHI TO M/S AL HABIB PHARMACEUTICALS, KARACHI DEFERRED IN 289TH MEETING OF REGISTRATION BOARD.

M/s Al-Habib Pharmaceuticals, Karachi applied for the registration of following human biological in their name from M/s Morgan Technologies Services, Karachi. The case was initially deferred in 262nd meeting as per following details:

Name of Manufacturer	Name of Drug and Composition& Reg. No.	Date of application / Fee status	Documentary details	Decision of RB in 262nd meeting
M/s GeneScience Pharmaceuticals Co. Ltd., 1718 Yueda Road, High-Tech Development Zone, Changchun, Jilin Province, China	SCIMAX Injection Recombinant Human Granulocyte Colony-Stimulating Factor Injection Each vial (1ml) contains: Recombinant Human Granulocyte Colony Stimulating Factor (rhG-CSF)…300ug/vial. Reg. No. 072504 Shelf life. 02years	Dy. No. 202 R&I DRAP dated 143-2016 Fee deposited Rs.15000/- dated 17-11-2011 + Rs. 35000/- dated 12-4-2013 + Rs.50000/- dated 13-11-2014	Legalized COPP No. 2014012 dated 25-6-2014 from china. Valid for two years.	Registration Board deferred for submission of biosimilarity data and valid legalized CoPP by the firm.

The firm then submitted valid legalized CoPP vide no. 2017005 dated 17-01-2017 valid for two years. The firm submitted the biosimilarity data on 17-01-2019 and now the CoPP is not valid. Moreover, the firm submitted that Scimax is a Biotherapeutic product and not a similar biotherapeutic product. It has 174 amino acids while all other branded Filgrastims including Neupogen have 175 amino acids and Scimax is a patent product. The application is for transfer of registration and the product was already registered in Pakistan.

The case was considered in 289th meeting of Registration Board wherein the Board decided as follows:

"Registration Board deferred the case for following:

a. Evaluation report of analytical parameters of the product in light of Pharmacopoeia.

b. Tabulated summary of non-clinical and clinical data submitted by the firm."

In this context, it is submitted that the Filgrastim Injection available in Pharmacopoeia has 175 amino acids while the applied product has 174 amino acids and the firm has already submitted that their product is patent. Tabulated summary of Non-clinical and clinical data submitted by the firm is as under:

Non-clinical In-vivo Studies c. Biological/ Pharmacodynamic activity d. Non- clinical toxicity as determined in one repeat dose toxicity study	Non-clinical Studies i. Study of anti-leucopenia effect of Scimax in Canis familiaris and Kunming hybrid mice in comparison with Filigsment of Kirin Japan ii. Non-comparative study of effects of Scimax on voluntary activities of mice iii. Non-comparative study of effects of Scimax on cardiovascular system and central nervous system of anesthetic cat Toxicology i. Non-comparative single dose toxicity study in mice ii. Non-comparative Long-term toxicity study in Beagle dogs iii. Non-comparative Long-term toxicity study in rats
Clinical	Only overview provided of following studies: i. Non-comparative Phase I (Pharmacokinetics & Pharmacodynamics) study of Scimax in healthy subjects. ii. Non-comparative Phase II study of Scimax. iii. Non-comparative Phase III study of Scimax iv. Multi-centre, randomized and controlled study of Scimax in comparison with imported Filgrastim. Details of imported Filgrastim are not provided by the firm.

Decision in 291st Registration Board meeting:

Registration Board deferred the case for submission, of evidence of availability of product in reference regulatory authorities, by the firm.

Response of firm:

Firm "M/s. Al Habib Pharmaceuticals" vide their reply dated March 14, 2024 has submitted following evidence:

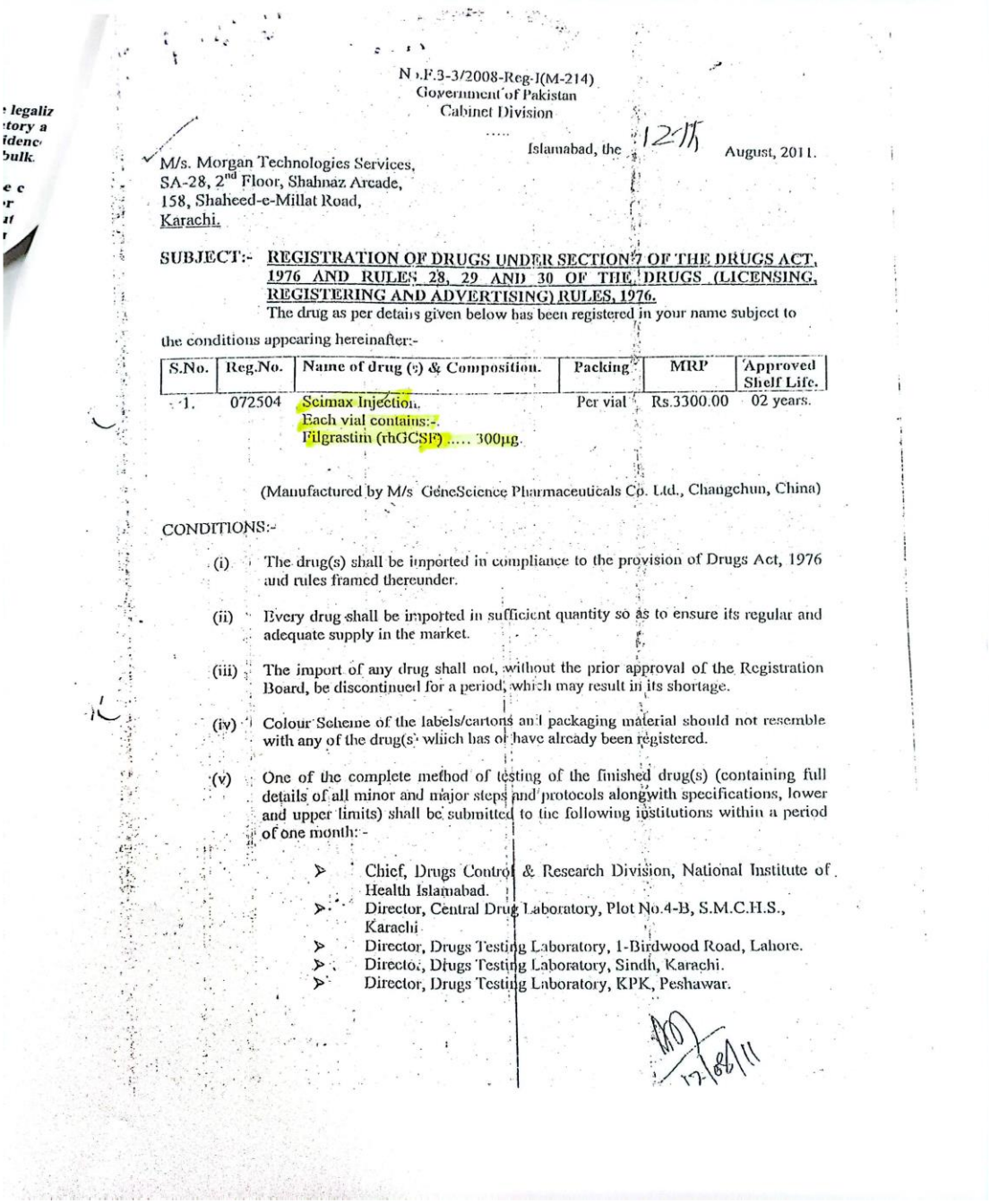
Drug Name	Active Ingredients	Strength	Dosage Form/Route	Drug Name/Approving Authority
Neupogen	Filgrastim	300MCG/1mL	Vial	USFDA

Firm has further submitted that there is a typographical error in the meeting minutes. The drug name Filgrastim (rfGCSF) is not mentioned instead its pharmacological class (Recombinant Human Granulocytes Colony Stimulating Factor-rfGCSF) is written it is kindly requested to make correction in your record.

Evaluation of BE&R Division:

i. It is submitted that the Filgrastim Injection available in USFDA website has 175 amino acids while the applied product has 174 amino acids.

ii. For typographic error firm has submitted copy of Registration letter as an evidence that Scimax Injection contains filgrastim.



No.F.3-3/2008-Reg-I(M-214)
Government of Pakistan
Cabinet Division
.....

Islamabad, the 12th August, 2011.

M/s. Morgan Technologies Services,
SA-28, 2nd Floor, Shahnaz Arcade,
158, Shaheed-e-Millat Road,
Karachi.

SUBJECT:- **REGISTRATION OF DRUGS UNDER SECTION 7 OF THE DRUGS ACT, 1976 AND RULES 28, 29 AND 30 OF THE DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976.**

The drug as per details given below has been registered in your name subject to the conditions appearing hereinafter:-

S.No.	Reg.No.	Name of drug (s) & Composition.	Packing	MRP	Approved Shelf Life.
1.	072504	Scimax Injection. Each vial contains:- Filgrastim (rhGCSF) ..... 300µg.	Per vial	Rs.3300.00	02 years.

(Manufactured by M/s GeneScience Pharmaceuticals Co. Ltd., Changchun, China)

CONDITIONS:-

(i) The drug(s) shall be imported in compliance to the provision of Drugs Act, 1976 and rules framed thereunder.

(ii) Every drug shall be imported in sufficient quantity so as to ensure its regular and adequate supply in the market.

(iii) The import of any drug shall not, without the prior approval of the Registration Board, be discontinued for a period, which may result in its shortage.

(iv) Colour Scheme of the labels/cartons and packaging material should not resemble with any of the drug(s) which has or have already been registered.

(v) One of the complete method of testing of the finished drug(s) (containing full details of all minor and major steps and protocols alongwith specifications, lower and upper limits) shall be submitted to the following institutions within a period of one month: -

- Chief, Drugs Control & Research Division, National Institute of Health Islamabad.
- Director, Central Drug Laboratory, Plot No.4-B, S.M.C.H.S., Karachi
- Director, Drugs Testing Laboratory, 1-Birdwood Road, Lahore.
- Director, Drugs Testing Laboratory, Sindh, Karachi.
- Director, Drugs Testing Laboratory, KPK, Peshawar.

12/8/11

Decision: The board keeping in view the data submitted by the firm and deliberations in the meeting decided to defer the case for the submission of comparative clinical studies

Miscellaneous cases:

14. APPLICATION FOR CHANGE IN ADDRESS OF IMPORTER OF M/S. CHIESI PHARMACEUTICAL PVT. LTD., FOR PRODUCT CUROSURF STERILE SUSPENSION IN VIALS FOR INTRATRACHEAL INSTILLATION APPROVED IN 271ST RB MEETING.

M/s. Chiesi Pharmaceutical Pvt. Ltd., has applied for change in address of importer.

Previous address:

60/1 A-XX, Phase-III, Commercial Zone

Khayaban-e-Iqbal, DHA, Lahore.
Gowdon Address: 14 Km Multan Road Near Thokar Niaz baig Lahore.

New address:
Office No: 4, 4th Floor, Askari Corporate Towers, 75/76 D-1, main Boulevard, Gulberg III, Lahore-54000.
Gowdon Address: Hall A, Khatooni No:66, Mauza Amer Kot, Thokar Niaz Baig, Multan Road, Lahore, Pakistan.
Following product was approved in 271st meeting of Registration as per following details:

Sr. No.	Brand Name and composition	Decision in 271st Registration Board meeting
1.	**Curosurf Sterile Suspension in vials for Intratracheal Instillation.** "Each vial contains: Poractant alfa… 240mg".	Registration Board took following decisions with regards to Curosurf Sterile Suspension (3ml): i. Approved the correction in composition of Curosurf Sterile suspension 3ml, as per CoPP as under: "Each vial contains: Poractant alfa… 240mg". ii. For the traceability of challan the procedure already prescribed in 264th meeting shall be followed. iii. A reference shall be sent to Costing and Pricing Division regarding price to given to the firm with the corrected composition i.e Each vial contains: Poractant alfa… 240mg.

The firm has applied for the change in address of importer and submitted following with their application:

a. Fee of 7500/- for change of address (Head office & Gowdown)
b. Previous DSL
c. New DSL valid

The details of previous and new DSLs are as under;

DSL	Title of the firm	Address
Previous	M/s. Chiesi Pharmaceutical Pvt. Ltd.,	60/1 A-XX, Phase-III, Commercial Zone Khayaban-e-Iqbal, DHA, Lahore. **Gowdon Address:** 14 Km Multan Road Near Thokar Niaz baig Lahore.
New	M/s. Chiesi Pharmaceutical Pvt. Ltd.,	**Office No:** 4, 4th Floor, Askari Corporate Towers, 75/76 D-1, main Boulevard, Gulberg III, Lahore-54000. **Gowdon Address:** Hall A, Khatooni No:66, Mauza Amer Kot, Thokar Niaz Baig, Multan Road, Lahore, Pakistan.

Decision: Registration Board approved the change of address of Importer from "60/1 A-XX, Phase-III, Commercial Zone Khayaban-e-Iqbal, DHA, Lahore. Gowdon Address: 14 Km Multan Road Near Thokar Niaz baig Lahore" to "Office No: 4, 4th Floor, Askari Corporate Towers, 75/76 D-1, main Boulevard, Gulberg III, Lahore-54000". Gowdon Address: Hall A, Khatooni No:66, Mauza Amer Kot, Thokar Niaz Baig, Multan Road, Lahore, Pakistan" subject to verification of cold storage facility.

15. Application for change in address of Importer M/s Pharmakon International Enterprises, for Product Foot and Mouth Disease Trivalent Vaccine, Inactivated (Strain O + Strain Asia 1+ Strain A) approved in 316th RB meeting.

M/s. Pharmakon International Enterprises has applied for change in address of importer.

Previous address:
M/s Pharmakon International Enterprises,
Office No. 26, 2nd Floor, Aries Plaza, Murree Road, Shamsabad.

New address: M/s Pharmakon International Enterprises,
Office No: 1st floor Hum Heights Service Road East, Sohan Islamabad.
Following product was approved in 316th meeting of Registration as per following details:

Sr. No.	Brand Name and composition	Decision in 316th Registration Board meeting
1.	Foot and Mouth Disease Trivalent Vaccine, Inactivated (Strain O + Strain Asia 1+ Strain A) Each dose contains: Inactivated FMD virus type A antigen ≥ 6PD50. Inactivated FMD virus type O antigen ≥ 6PD50. Inactivated FMD virus type Asia 1 antigen ≥ 6PD50.	Keeping in view legalized GMP and FSC indicating product availability in country of origin and approval of Italy (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit valid legalized GMP certificate before issuance of registration letter. Chairman Registration Board is authorized for issuance of registration letter after submission of GMP certificate by the firm.

The firm has applied for the change in address of importer and submitted following with their application:

a. Fee of 7500/- for change of address
b. Previous DSL
c. New DSL valid

The details of previous and new DSLs are as under;

DSL	Title of the firm	Address
Previous	M/s Pharmakon International Enterprises,	Office No. 26, 2nd Floor, Aries Plaza, Murree Road, Shamsabad..
New	M/s Pharmakon International Enterprises,	M/s Pharmakon International Enterprises, Office No: 1st floor Hum Heights Service Road East, Sohan Islamabad.Gowdon.

Decision: Registration Board approved the change of address of Importer from "Office No. 26, 2nd Floor, Aries Plaza, Murree Road, Shamsabad" to "1st floor Hum Heights Service Road East, Sohan Islamabad" subject to verification of cold storage facility.

CASES OF DD-III (MS. ANUM SAEED)

A. Imported Veterinary Biologicals from Non-Reference Countries:

16.	**Name of Applicant**	UMEX Biopharma Pvt. Limited, Plot No.44 A & 45 A NACLASS No.24, DEH DIL TALUKS. Korangi Industrial Area. Karachi, Pakistan.
	DSL details	DSL License No. 579 valid upto 12-09-2024.
	Name of Manufacturer and MA Holder	PT VAKSINDO SATWA NUSANTARA (Plant 2) Jl. Barokah Wanaherang, Gunung putri, Bogor, West Java 16965, Indonesia

	Name of exporting country	**Indonesia**
	Brand Name + Dosage Form + Strength	**Vaksimune IBD M + (1000 Doses)** Live Vaccine, Freeze Dried
	Composition	Each dose of Freeze-Dried Vaccine contains; Infectious Bursal Disease virus of Moulthrop (Intermediate Plus) strain at least…… $10^{2.0}$ EID_{50}
	Finished product specifications	Indonesian Pharmacopeia
	Pharmacological Group	Vaccine
	Shelf life	24 Months (Store at 2°C to 8°C)
	International availability	Cambodia, Vietnam, Egypt, Nepal, and Myanmar
	Alternate Products already registered in Pakistan	BURSA-VAC of M/s Merck Animal Health imported by M/s ICI Pakistan Limited.
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A Dy.No.13255(R&I) DRAP dated 31-05-2022. Fee of PKR75,000/- Challan No. 68777644 dated 23-05-2022. Differential Fees of PKR75,000/- Challan No. 355387230688 dated 13-09-2023
	Demanded Price Pack size	De-controlled **1000 doses**
	General Documentation	1. Legalized Certificate of Registration and Free Sale Ref. No. 07017/PI.500/F/12/2020 dated 07-12-2020 issued by Ministry of Agriculture, Directorate General of Livestock and Animal Health Services, Indonesia. 2. Apostille Letter of Authorization Valid till 31-07-2024.
	Evaluator Comments	The product monograph is available in British Pharmacopoeia, but the manufacturer has developed the product as per Indonesian Pharmacopoeia.
	Decision: On the basis of documents/information/data along with legalized Certificate of Registration and free sale certificate indicating product availability in country of origin submitted by the applicant, the Registration Board approved the product with Indonesian Pharmacopoeia Specifications subject to compliance of current Import Policy for finished drugs.	

17.	**Name of Applicant**	UMEX Biopharma Pvt. Limited, Plot No.44 A & 45 A NACLASS No.24, DEH DIL TALUKS. Korangi Industrial Area. Karachi, Pakistan.
	DSL details	DSL License No. 579 valid upto 12-09-2024.
	Name of Manufacturer and MA Holder	PT VAKSINDO SATWA NUSANTARA (Plant 2) Jl. Barokah Wanaherang, Gunung putri, Bogor, West Java 16965, Indonesia
	Name of exporting country	**Indonesia**
	Brand Name + Dosage Form + Strength	**Vaksimune IBD M + (2000 Doses)** Live Vaccine, Freeze Dried
	Composition	Each dose of the Vaccine contains. Infectious Bursal Disease virus of Moulthrop (Intermediate Plus) strain at least…… $10^{2.0}$ EID_{50}

	Finished product specifications	Indonesian Pharmacopeia
	Pharmacological Group	Vaccine
	Shelf life	24 Months (Store at 2°C to 8°C)
	International availability	Cambodia, Vietnam, Egypt, Nepal, and Myanmar
	Alternate Products already registered in Pakistan	BURSA-VAC of M/s Merck Animal Health imported by M/s ICI Pakistan Limited.
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A Dy.No.13256(R&I) DRAP dated 31-05-2022. Fee of PKR75,000/- Challan No. 8614880814 dated 23-05-2022. Differential Fees of PKR75,000/- Challan No. 558806968890 dated 13-09-2023
	Demanded Price Pack size	De-controlled **2000 doses**
	General Documentation	1. Legalized Certificate of Registration and Free Sale Ref. No. 07017/PI.500/F/12/2020 dated 07-12-2020 issued by Ministry of Agriculture, Directorate General of Livestock and Animal Health Services, Indonesia. 2. Apostille Letter of Authorization Valid till 31-07-2024.
	Evaluator Comments	The product monograph is available in British Pharmacopoeia, but the manufacturer has developed the product as per Indonesian Pharmacopoeia.
1.	**Decision: Keeping in view above; Registration Board after deliberation, legalized CoPP and availability of product in country of origin, the Registration Board approved the product with Indonesian Pharmacopoeia Specifications subject to compliance of current Import Policy for finished drugs.**	

18.	**Name of Applicant**	UMEX Biopharma Pvt. Limited, Plot No.44 A & 45 A NACLASS No.24, DEH DIL TALUKS. Korangi Industrial Area. Karachi, Pakistan.
	DSL details	DSL License No. 579 valid upto 12-09-2024.
	Name of Manufacturer and MA Holder	**PT VAKSINDO SATWA NUSANTARA (**Plant 2) Jl. Barokah Wanaherang, Gunung putri, Bogor, West Java 16965, Indonesia
	Name of exporting country	**Indonesia**
	Brand Name + Dosage Form + Strength	**VAKSIMUNE NDHV IB (1000 Doses)** Live Vaccine, Freeze Dried
	Composition	Each dose contains: Newcastle Disease virus of Ulster strain At least……. $10^{6.5}$ EID_{50} Infectious Bronchitis virus of H120 strain $10^{2.9}$ EID_{50}
	Finished product specifications	Indonesian Pharmacopeia
	Pharmacological Group	Vaccine
	Shelf life	24 Months (Store at 2°C to 8°C)
	International availability	Cambodia, Vietnam, Egypt, Nepal, and Myanmar

	Alternate Products already registered in Pakistan	Gallimune 302 ND IB EDS by M/s Saadat International, contains Inactivated Newcastle Disease virus, Ulster 2C strain. Hipraviar B1/H120 by M/s Hipra Laboratories, contains Live Infectious Bronchitis Virus, attenuated H120 strain
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A Dy.No.13254(R&I) DRAP dated 31-05-2022. Fee of PKR75,000/- Challan No. 49617236995 dated 23-05-2022. Differential Fees of PKR75,000/- Challan No. 79591888480 dated 13-09-2023
	Demanded Price Pack size	De-controlled
	General Documentation	2. Legalized Certificate of Registration and Free Sale Ref.No.31044/PI.500/F/08/2020 dated 31-08-2020 issued by Ministry of Agriculture, Directorate General of Livestock and Animal Health Services, Indonesia. 3. Apostile Letter of Authorization Valid till 31-07-2024.
	Evaluator Comments	• The product monograph is available in British Pharmacopoeia, but the manufacturer has developed the product as per Indonesian Pharmacopoeia. • The applied strains are registered separately in different products as mentioned above but the combination of Newcastle Disease virus of **Ulster strain** and Infectious Bronchitis virus of **H120 strain** are not registered before.
	Decision: Decision: Keeping in view above; Registration Board after deliberation, legalized CoPP and availability of product in country of origin and on the basis of expert opinion by "Dr. Qurban, expert coopted member Registration Board", the Registration Board approved the product with Indonesian Pharmacopoeia Specifications, subject to compliance of current Import Policy for finished drugs.	

19.	**Name of Applicant**	UMEX Biopharma Pvt. Limited, Plot No.44 A & 45 A NACLASS No.24, DEH DIL TALUKS. Korangi Industrial Area. Karachi, Pakistan.
	DSL details	DSL License No. 579 valid upto 12-09-2024.
	Name of Manufacturer and MA Holder	**PT VAKSINDO SATWA NUSANTARA** (Plant 1) Jl. Mercedes Benz No. 12 Cicadas, Gunung Putri, Bogor, West Java 16964, Indonesia
	Name of exporting country	**Indonesia**
	Brand Name + Dosage Form + Strength	**VAKSIMUNE ND L Inaktif 0.1 (5000 Doses)** Inactivated Vaccine in Oil Emulsion
	Composition	Each dose of the vaccine contains: Newcastle Disease Genotype VII virus of N018 strain at least……$10^{8.3}EID_{50}$
	Finished product specifications	Indonesian Pharmacopeia
	Pharmacological Group	Vaccine
	Shelf life	24 Months (Store at 2^oC to 8^oC)
	International availability	Cambodia, Vietnam, Egypt, Nepal, and Myanmar
	Alternate Products already registered in Pakistan	The applied strain is not registered as per data available
	Type of Form	Form 5-A

	Dy. No. Date of Application, Fee submitted	Dy.No.13402(R&I) DRAP dated 02-06-2022. Slip Number: 599925048 of PKR150,000/- dated 23-05-2022.
	Demanded Price Pack size	5000 doses Decontrolled
	General Documentation	• Legalized Certificate of Registration and Free Sale Ref. No. 300057/PI.500/F/09/2021 dated 30-09-2021 issued by Ministry of Agriculture, Directorate General of Livestock and Animal Health Services, Indonesia. • Apostile Letter of Authorization Valid till 31-07-2024
	Evaluator Comments	• The applied strain is not registered as per data available. • The product monograph is available in British Pharmacopoeia, but the manufacturer has developed the product as per Indonesian Pharmacopoeia.
	Decision: Decision: Keeping in view above; Registration Board after deliberation, legalized CoPP and availability of product in country of origin and on the basis of expert opinion by "Dr. Qurban, expert coopted member Registration Board", the Registration Board approved the product with Indonesian Pharmacopoeia Specifications, subject to compliance of current Import Policy for finished drugs.	

20.	**Name of Applicant**	UMEX Biopharma Pvt. Limited, Plot No.44 A & 45 A NACLASS No.24, DEH DIL TALUKS. Korangi Industrial Area. Karachi, Pakistan.
	DSL details	DSL License No. 579 valid upto 12-09-2024.
	Name of Manufacturer and MA Holder	**PT VAKSINDO SATWA NUSANTARA** (Plant 1) Jl. Mercedes Benz No. 12 Cicadas, Gunung Putri, Bogor, West Java 16964, Indonesia.
	Name of exporting country	**Indonesia**
	Brand Name + Dosage Form + Strength	**VAKSIMUNE ND L Inaktif 0.1 (2000 Doses)** Inactivated Vaccine in Oil Emulsion
	Composition	Each dose of the vaccine contains: Newcastle Disease Genotype VII virus of N018 strain at least……$10^{8.3}EID_{50}$
	Finished product specifications	Indonesian Pharmacopeia
	Pharmacological Group	Vaccine
	Shelf life	24 Months (Store at 2^oC to 8^oC)
	International availability	Cambodia, Vietnam, Egypt, Nepal, and Myanmar
	Alternate Products already registered in Pakistan	The applied strain is not registered as per data available
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A Dy.No.13401(R&I) DRAP dated 02-06-2022. Slip Number: 6732290991 of PKR150,000/- dated 23-05-2022.
	Demanded Price Pack size	2000 doses Decontrolled
	General Documentation	• Legalized Certificate of Registration and Free Sale Ref. No. 300057/PI.500/F/09/2021 dated 30-09-2021 issued by Ministry of

		Agriculture, Directorate General of Livestock and Animal Health Services, Indonesia. • Apostile Letter of Authorization Valid till 31-07-2024
	Evaluator Comments	• The applied strain is not registered as per data available. • The product monograph is available in British Pharmacopoeia, but the manufacturer has developed the product as per Indonesian Pharmacopoeia.
	Decision: Decision: Keeping in view above; Registration Board after deliberation, legalized CoPP and availability of product in country of origin and on the basis of expert opinion by "Dr. Qurban, expert coopted member Registration Board", the Registration Board approved the product with Indonesian Pharmacopoeia Specifications, subject to compliance of current Import Policy for finished drugs.	

B. <u>Imported Human Biologicals from Reference Countries</u>

21.	**Name, address of Applicant / Importer**	**Lundbeck Pakistan (Private) Limited** **40T/4, Blessing Street,** **Block 6, P.E.C.H.S. Karachi** **Pakistan**
	Details of Drug Sale License of importer	License # 0253 Lundbeck Pakistan (Private) Limited <u>Godown address</u>: 1st & 2nd Floor, F-243/D Site Near Labar Square, Karachi Validity 31-7-2024
	Name and address of marketing authorization holder (abroad)	M/s H. Lundbeck A/S, Ottiliavej 9, 2500 Valby, Denmark
	Name, address of manufacturer(s)	**Manufacturing Site:** M/s Vetter Pharma Fertigung GmbH & CO. KG Mooswiesen 2, Ravensburg Baden-Wuerttemberg 88214, Germany **Site Responsible for Secondary Packaging and Release:** <u>H. Lundbeck A/S</u> Ottiliavej 92500 Valby <u>Denmark</u>.
	Name of exporting country	**Denmark**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted Legalized CoPP (No. 06/22/176382) dated 08.11.2022 issued by EUROPEAN MEDICINES AGENCY, DOMENICO SCARLATTILAAN 6, 1083 HS AMSTERDAM, THE NETHERLANDS. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection.

	Details of letter of authorization / sole agency agreement	Firm has submitted Original LETTER OF AUTHORIZATION dated 14-11-2022 issued by the marketing authorization holder H. Lundbeck A/S, Ottiliavej 9, 2500 Valby, Denmark, (Valid for 2 years).
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import. ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and Date of submission	Dy. No. 399, Dated 05-01-2023
	Details of fee submitted	PKR 75,000/- Dated 4-1-2023 Challan # 90036055455
	The proposed proprietary name / brand name	**Vyepti 100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL contains: Eptinezumab……..100mg
	Pharmaceutical form of applied drug	**Concentrate for solution for infusion**
	Pharmacotherapeutic Group of (API)	Monoclonal antibody
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	1mL Vial
	Proposed unit price	As per SRO
	Shelf Life	3 Years
	Storage Condition	Store between 2°C to 8°C
	The status in reference regulatory authorities	Vyepti registered in EU
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per Innovator template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Name, address of drug substance manufacturer	M/s Sandoz GmbH Biochemiestrasse 10 Kundl 6250 Austria
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and Long term conditions. The accelerated stability study data is conducted at 5°C ± 3°C and at 0,1,3, and 6 months. The Long Term stability data is conducted at < -60^{0}C at 0,3,6,9,12,1,8,24,31,36,48 and 60 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	The primary container closure system consists of Type I glass vials with a 13 mm neck size and a 13 mm diameter chlorobutyl rubber stopper. The stopper is kept in its position by an aluminum seal with a flip-off plastic cap. The seal does not come into contact with the drug product itself.
	Stability study data of drug product, shelf life and storage conditions	The accelerated stability study data of three batches is conducted at 25°C ± 2°C / 60% RH ± 5% RH at 0,1,3 and 6 Months. The long Term stability study data of three batches is conducted at 5°C ± 3°C at 0,1,3,6,9,12,18,24,30,36 and 48 months
	Module IV	Firm has submitted the following; • Single dose toxicity studies in rats and cynomolgus monkeys. • Repeat dose toxicity studies in rats and cynomolgus monkeys.
	Module V	Firm has submitted the following data; • 7 phase-1 studies were conducted in healthy subjects. • 2 phase-1 studies were conducted in patients with other disease states/conditions. • A Phase 3, parallel group, double blind, randomized, placebo-controlled trial in 888 number of subjects to evaluate efficacy and safety of Eptinezumab administered IV in patients with frequent episodic migraines. • A Phase 3, parallel group, double-blind, randomized placebo controlled trial in 1072 number of subjects to evaluate the efficacy and safety of Eptinezumab administered intravenously in patients with chronic migraine.
Decision: Keeping in view above; Registration Board after deliberation, legalized CoPP issued by EMA indicating product availability in European Union, Registration Board approved the registration of		

VYEPTI 100mg concentrate for solution for infusion subject to compliance of current import policy for finished products.

22.	**Name, address of Applicant / Importer**	**Martin Dow Specialties (Pvt.) Ltd.** Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S., Razi Road, Shahrah-e-Faisal, Karachi, Pakistan.
	Details of Drug Sale License of importer	License No: 0186 **Address:** 7th Floor, Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S, Razi Road, Shahrah-e-Faisal, Karachi **Validity**: 07/12/2026
	Name and address of marketing authorization holder (abroad)	M/s Merck Europe B.V., Gustav Mahlerplein 102, 1081 MA Amsterdam, The Netherlands.
	Name, address of manufacturer(s)	**Manufacturing Site/Batch Release Site:** M/s Merck Serono S.p.A., Via Delle Mangnolie, 15 (loc. Frazione Zona Industriale), 70026 – Modugna (BA), Italy. **Site responsible for QC:** M/s Merck Serono S.p.A., Guidonia Montecelio Site, Via Luigi Einaudi, 11, 00012 Guidonia Notecelio (RM), Italy. **Site responsible for secondary packaging:** M/s Merck Serono S.p.A., Succursale d'Aubonne, Zone Industrielle de 1170 Aubonne, Switzerland.
	Name of exporting country	**Italy**
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No. 03/22/171150) dated 27-06-2022 issued by European Medicines Agency, Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands. The COPP specifiesthat the product is licensed for sale in the country of origin. The COPP also specifies the GMP status of manufacturer.
	Details of letter of authorization/ sole agency agreement	Firm has submitted legalized Distribution Certificate from **M/s** Merck Europe B.V.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only

Dy. No. and date of submission	Form -5F Dy. No.:29795 R&I dated: 20/10/2022
Details of fee submitted	Rs: 150,000 Dated: 27/09/2022 Deposit Slip No. 477705342
The proposed proprietary name / brand name	**Pergoveris (300 IU+ 150 IU)/0.48 mL Solution for Injection in a Prefilled Pen.**
Strength / concentrationof drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled pen contains 300 IU (equivalent to 22 micrograms) of follitropin alfa (r-hFSH) and 150 IU (equivalent to 6 micrograms) of lutropin alfa (r-hLH) in 0.48 mL.
Dosage form of applied drug	Solution for Injection in a Pre-Filled Pen
Pharmacotherapeutic Group of (API)	Gonadotropins
Reference to Finished product specifications	Innovator's Specifications
Proposed Pack size	**1 Pre-filled Pen + 5 needles**
Proposed unit price	As per SRO
Shelf Life	12 months
Storage Conditions	2–8 °C
The status in reference regulatory authorities	Pergoveris Solution for Injection (EMA)
For generic drugs (me-too status)	N/A
Module-II (QualityOverall Summary)	The firm has submitted QOS as per ICH guidelines. Firm has summarized information related to general properties, manufacturers, description of manufacturing process and controls, characterization, specifications analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.

Name, address of drugsubstance manufacturer	Name: Merck Serono S.A., Address: Succursale d'Aubonne, Zone Industrielle de l'Ouriettaz, CH-1170, Aubonne, Switzerland.
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, container closure system.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Folitropin alfa** Firm has submitted stability data of 3 batches as; Long term stability data (-20°C ± 5°C) at 0,3,6,9,12,18,24,36,48 and 60 months. Accelerated stability study (+5°C ± 3°C) at 0,1,2,3 and 6 months. **Lutropin Alfa** Firm has submitted stability data of 3 batches as; Long term stability data (-20°C ± 5°C) at 0,3,6,9,12,18,24,36,48 and 60 months. Accelerated stability study (+5°C ± 3°C) at 0,1,3 and 6 months
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Analytical method validation/verification of product	Method verification was carried out for identification, Bacterial Endotoxins, Clarity and degree of Opalescence, Compendial, Degree of coloration, osmotic pressure molar concentration, in vivo bioactivity in the drug product, Extractable Volume for Pre-filled Pen, Oxidised forms, Identification & Assay of Phenol by GC, sterility test and bacterial endotoxin test, Determination of Aggregates and Dissociated Subunits by SDS-PAGE / Silver Stain were carried out.
Container closure system of the drug product	The primary container is a colourless type I borosilicate glass barrel cartridge (Ph.Eur., USP) with a nominal capacity of 3 mL. The closure consists of two components: • A grey bromobutyl rubber plunger stopper • A crimp cap made with grey rubber stopper septum and aluminum. The plunger stopper and the crimp cap are made of elastomer complying with Ph. Eur. and USP current edition.
Stability study data ofdrug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches at real time and accelerated conditions. The real time stability data provided is conducted at (+5°C ± 3°C) at 0,3,6,9,12,18,24,30 and 36 months. The accelerated stability data provided is of 03 batches and is conducted at (25°C ± 2°C 60%RH ± 5%) at 0,2,3 and 6 months.
Module-IV (Non-Clinical)	Firm has submitted. Efficacy of r-hFSH in LH-deficient Monkeys Active systemic anaphylaxis study in guinea pigs. R-hFSH Biopotency in the Granulosa Cell Aromatase Bioassay Pharmacodynamics of R-hFSH in Female Monkeys. Single dose and repeat dose toxicity studies in Rats by IV and

	subcutaneous route.
Module-V (Clinical)	**The relative bioavailability of the constituent gonadotropins were compared to the individually approved products containing separately follitropin alfa and leutropin alfa in biopharmaceutical studies** (IMP23718 and IMP23722). These two new clinical studies were run in healthy female subjects to allow separate investigation of bioavailability for follitropin alfa and leutropin alfa. IMP23718 was a randomized double blind, 2-way cross over study in which 36 healthy female subjects were down regulated using the GnRH-agonist goserelin. IMP23722 was a 2-arm-cross-over, open label study in in which 81 healthy female subjects were down regulated using the GnRH-agonist goserelin regulated. Firm has submitted the following; A phase II/III, an open, randomised, dose-finding, multicenter study to determine the minimal effective dose and to assess the safety of r-hLH to support r-hFSH-induced follicular development in anovulatory women with hypogonadotropic hypogonadism in 40 number of subjects. A Phase III multicenter, non-comparative study to evaluate the efficacy and safety of r-hLH to support r-hFSH-induced follicular development in LH and FSH deficient anovulatory women (WHO Group I) in 38 number of subjects. A phase III multicenter study for the evaluation of the efficacy and safety of r-hLH to support r-hFSH induced follicular development in LH and FSH deficient anovulatory women (WHO group I) in 15 number of subjects. A phase III, prospective, randomized, controlled, double-blind, multicenter study to confirm the efficacy and safety of r-hLH, 75 IU, administered subcutaneously, to support r-hFSH-induced follicular development in women with hypogonadotropic hypogonadism and severe LH deficiency who desire pregnancy in 39 number of subjects.
Decision: Keeping in view above; Registration Board after deliberation, legalized CoPP issued by EMA indicating product availability in European Union, Registration Board approved the product subject to compliance of current import policy for finished products.	

23.	**Name, address of Applicant/ Importer**	**Martin Dow Specialities (Pvt.) Ltd.** Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S., Razi Road, Shahrah-e-Faisal, Karachi, Pakistan.
	Details of Drug Sale License of importer	License No: 0186 **Address:** 7th Floor, Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S, Razi Road, Shahrah-e-Faisal, Karachi **Validity:** 07/12/2026
	Name and address of marketing authorization holder (abroad)	M/s Merck Europe B.V., Gustav Mahlerplein 102, 1081 MA Amsterdam, The Netherlands.

	Name, address of manufacturer(s)	**Manufacturing Site/Batch Release Site:** M/s Merck Serono S.p.A., Via Delle Mangnolie, 15 (loc. Frazione Zona Industriale), 70026 – Modugna (BA), Italy. **Site responsible for QC:** M/s Merck Serono S.p.A., Guidonia Montecelio Site, Via Luigi Einaudi, 11, 00012 Guidonia Notecelio (RM), Italy. **Site responsible for secondary packaging:** M/s Merck Serono S.p.A., Succursale d'Aubonne, Zone Industrielle de 1170 Aubonne, Switzerland.
	Name of exporting country	**Italy**
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No. 03/22/171150) dated 27-06-2022 issued byEuropean Medicines Agency, Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands. The COPP specifiesthat the product is licensed for sale in the country of origin. The COPP also specifies the GMP status of manufacturer.
	Details of letter of authorization/sole agency agreement	Firm has submitted legalized Distribution Certificate from **M/s** Merck Europe B.V.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only

Dy. No. and date of submission	Form -5F Dy. No.: 29796 R&I dated: 20/10/2022
Details of fee submitted	Rs: 150,000 Dated: 27/09/2022 Deposit Slip No. 306635183357
The proposed proprietary name / brand name	**Pergoveris (450 IU+ 225 IU)/0.72 mL Solution for Injection in a Prefilled Pen**
Strength / concentration of drug of Active Pharmaceutical ingredient(API) per unit	Each pre-filled pen contains 450 IU (equivalent to 33 micrograms) of follitropin alfa (r-hFSH) and 225 IU (equivalent to 9 micrograms) of lutropin alfa (r-hLH) in 0.72 mL.
Dosage form of applied drug	Solution for Injection in a Pre-Filled Pen
Pharmacotherapeutic Group of (API)	Gonadotropins
Reference to Finished product specifications	Innovator's Specifications
Proposed Pack size	**1 Pre-filled Pen + 7 needles**
Proposed unit price	As per SRO
Shelf Life	12 months
Storage Conditions	2–8 °C
The status in reference regulatory authorities	Pergoveris Solution for Injection (EMA)
For generic drugs (me-too status)	N/A
Module-II (Quality Overall Summary)	The firm has submitted QOS as per ICH guidelines. Firm has summarized information related to general properties, manufacturers, description of manufacturing process and controls, characterization, specifications analytical procedures and its validation, batch analysis and justification of specification, referencestandard, container closure system and stability studies of drugsubstance and drug product. The firm has also submitted the non- clinical and clinical overviews and summaries.

Name, address of drug substance manufacturer	Name: Merck Serono S.A., Address: Succursale d'Aubonne, Zone Industrielle de l'Ouriettaz, CH-1170, Aubonne, Switzerland.
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, container closure system.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Folitropin alfa** Firm has submitted stability data of 3 batches as; Long term stability data (-20°C ± 5°C) at 0,3,6,9,12,18,24,36,48 and 60 months. Accelerated stability study (+5°C ± 3°C) at 0,1,2,3 and 6 months. **Lutropin Alfa** Firm has submitted stability data of 3 batches as; Long term stability data (-20°C ± 5°C) at 0,3,6,9,12,18,24,36,48 and 60 months. Accelerated stability study (+5°C ± 3°C) at 0,1,3 and 6 months
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Analytical method validation/verification of product	Method verification was carried out for identification, Bacterial Endotoxins, Clarity and degree of Opalescence, Compendial, Degree of coloration, osmotic pressure molar concentration, in vivo bioactivity in the drug product, Extractable Volume for Pre-filled Pen, Oxidised forms, Identification & Assay of Phenol by GC, sterilitytest and bacterial endotoxin test, Determination of Aggregates and Dissociated Subunits by SDS-PAGE / Silver Stain were carried out.
Container closure system of thedrug product	The primary container is a colourless type I borosilicate glass barrel cartridge (Ph.Eur., USP) with a nominal capacity of 3 mL. The closure consists of two components: • A grey bromobutyl rubber plunger stopper • A crimp cap made with grey rubber stopper septum and aluminum. The plunger stopper and the crimp cap are made of elastomer complying with Ph. Eur. and USP current edition.
Stability study data ofdrug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches at real time andaccelerated conditions. The real time stability data provided is conducted at (+5°C ± 3°C) at 0,3,6,9,12,18,24,30 and 36 months. The accelerated stability data provided is of 03 batches and is conducted at (25°C ± 2°C 60%RH ± 5%) at 0,2,3 and 6 months.

Module-IV (Non-Clinical)	Firm has submitted: Efficacy of r-hFSH in LH-deficient Monkeys Active systemic anaphylaxis study in guinea pigs. R-hFSH Biopotency in the Granulosa Cell Aromatase Bioassay Pharmacodynamics of R-hFSH in Female Monkeys. Single dose and repeat dose toxicity studies in Rats by IV and subcutaneous route.
Module-V (Clinical)	The relative bioavailability of the constituent gonadotropins was compared to the individually approved products containing separately follitropin alfa and leutropin alfa in biopharmaceutical studies (IMP23718 and IMP23722). These two new clinical studies were run in healthy female subjects to allow separate investigation of bioavailability for follitropin alfa and leutropin alfa. IMP23718 was a randomized double blind, 2-way cross over study in which 36 healthy female subjects were down regulated using the GnRH-agonist goserelin. IMP23722 was a 2-arm-cross-over, open label study in in which 81 healthy female subjects were down regulated using the GnRH-agonist goserelin. regulated Firm has submitted the following; • A phase II/III, an open, randomised, dose-finding, multicenter study to determine the minimal effective dose and to assess the safety of r-hLH to support r-hFSH-induced follicular development in anovulatory women with hypogonadotropic hypogonadism in 40 number of subjects. • A Phase III multicenter, non-comparative study to evaluate the efficacy and safety of r-hLH to support r-hFSH-induced follicular development in LH and FSH deficient anovulatory women (WHO Group I) in 38 number of subjects. • A phase III multicenter study for the evaluation of the efficacy and safety of r-hLH to support r-hFSH induced follicular development in LH and FSH deficient anovulatory women (WHO group I) in 15 number of subjects. • A phase III, prospective, randomized, controlled, double-blind, multicenter study to confirm the efficacy and safety of r-hLH, 75 IU, administered subcutaneously, to support r-hFSH-induced follicular development in women with hypogonadotropic hypogonadism and severe LH deficiency who desire pregnancy in 39 number of subjects.
Decision: Keeping in view above; Registration Board after deliberation, legalized CoPP issued by EMA indicating product availability in European Union, Registration Board approved the product subject to compliance of current import policy for finished products.	

24.	**Name, address of Applicant / Importer**	Martin Dow Specialities (Pvt.) Ltd. Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S., Razi Road, Shahrah-e-Faisal, Karachi, Pakistan.

	Details of Drug Sale License of importer	License No: 0186 **Address:** 7th Floor, Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S, Razi Road, Shahrah-e-Faisal, Karachi Validity: 07/12/2026
	Name and address of marketing authorizatio nholder (abroad)	M/s Merck Europe B.V., Gustav Mahlerplein 102, 1081 MA Amsterdam, The Netherlands.
	Name, address of manufacturer(s)	**Manufacturing Site/Batch Release Site:** M/s Merck Serono S.p.A., Via Delle Mangnolie, 15 (loc. Frazione Zona Industriale), 70026 – Modugna (BA), Italy. **Site responsible for QC:** M/s Merck Serono S.p.A., Guidonia Montecelio Site, Via Luigi Einaudi, 11, 00012 Guidonia Notecelio (RM), Italy. **Site responsible for secondary packaging:** M/s Merck Serono S.p.A., Succursale d'Aubonne, Zone Industrielle de 1170 Aubonne, Switzerland.
	Name of exportingcountry	**Italy**
	Detail of certificatesattached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No. 03/22/171150) dated 27-06-2022 issued by European Medicines Agency, Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands. The COPP specifies that the product is licensed for sale in the country of origin. The COPP also specifies the GMP status of manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized Distribution Certificate from **M/s** Merck Europe B.V.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only

Dy. No. and date of submission	Form -5F Dy. No.: 29797 R&I dated: 20/10/2022
Details of fee submitted	Rs: 150,000 Dated: 27/09/2022 Deposit Slip No. 990909675795
The proposed proprietary name / brand name	**Pergoveris (900 IU+ 450 IU)/1.44 mL Solution for Injection in a Prefilled Pen**
Strength / concentrationof drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled pen contains 900 IU (equivalent to 66 micrograms) of follitropin alfa (r-hFSH) and 450 IU (equivalent to 18 micrograms) of lutropin alfa (r-hLH) in 1.44 mL.
Dosage form of applied drug	Solution for Injection in a Pre-Filled Pen
Pharmacotherapeutic Group of (API)	Gonadotropins
Reference to Finished product specifications	Innovator's Specifications
Proposed Pack size	**1 pre-filled pen + 14 needles**
Proposed unit price	As per SRO
Shelf Life	12 months
Storage Conditions	2–8 °C
The status in reference regulatory authorities	Pergoveris Solution for Injection (EMA)
For generic drugs (me-too status)	N/A
Module-II (Quality Overall Summary	The firm has submitted QOS as per ICH guidelines. Firm has summarized information related to general properties, manufacturers, description of manufacturing process and controls, characterization, specifications analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.

Name, address of drug substance manufacturer	Name: Merck Serono S.A., Address: Succursale d'Aubonne, Zone Industrielle de l'Ouriettaz, CH-1170, Aubonne, Switzerland.
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, container closure system.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Folitropin alfa** Firm has submitted stability data of 3 batches as; Long term stability data (-20°C ± 5°C) at 0,3,6,9,12,18,24,36,48 and 60 months. Accelerated stability study (+5°C ± 3°C) at 0,1,2,3 and 6 months. **Lutropin Alfa** Firm has submitted stability data of 3 batches as; Long term stability data (-20°C ± 5°C) at 0,3,6,9,12,18,24,36,48 and 60 months. Accelerated stability study (+5°C ± 3°C) at 0,1,3 and 6 months
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Analytical method validation/verification of product	Method verification was carried out for identification, Bacterial Endotoxins, Clarity and degree of Opalescence, Compendial, Degree of coloration, osmotic pressure molar concentration, in vivo bioactivity in the drug product, Extractable Volume for Pre-filled Pen, Oxidised forms, Identification & Assay of Phenol by GC, sterilitytest and bacterial endotoxin test, Determination of Aggregates and Dissociated Subunits by SDS-PAGE / Silver Stain were carried out.
Container closure system of the drug product	The primary container is a colourless type I borosilicate glass barrel cartridge (Ph.Eur., USP) with a nominal capacity of 3 mL. The closure consists of two components: • A grey bromobutyl rubber plunger stopper • A crimp cap made with grey rubber stopper septum and aluminum. The plunger stopper and the crimp cap are made of elastomer complying with Ph. Eur. and USP current edition.

Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches at real time and accelerated conditions. The real time stability data provided is conducted at (+5°C ± 3°C) at 0,3,6,9,12,18,24,30 and 36 months. The accelerated stability data provided is of 03 batches and is conducted at (25°C ± 2°C 60%RH ± 5%) at 0,2,3 and 6 months.
Module-IV (Non-Clinical)	Firm has submitted. Efficacy of r-hFSH in LH-deficient Monkeys Active systemic anaphylaxis study in guinea pigs. R-hFSH Biopotency in the Granulosa Cell Aromatase Bioassay Pharmacodynamics of R-hFSH in Female Monkeys. Single dose and repeat dose toxicity studies in Rats by IV and subcutaneous route.
Module-V (Clinical)	The relative bioavailability of the constituent gonadotropins were compared to the individually approved products containing separately follitropin alfa and leutropin alfa in biopharmaceutical studies (IMP23718 and IMP23722). These two new clinical studies were run in healthy female subjects to allow separate investigation of bioavailability for follitropin alfa and leutropin alfa. IMP23718 was a randomized double blind, 2-way cross over study in which 36 healthy female subjects were down regulated using the GnRH-agonist goserelin. IMP23722 was a 2-arm-cross-over, open label study in in which 81 healthy female subjects were down regulated using the GnRH-agonist goserelin. regulated Firm has submitted the following; • A phase II/III, an open, randomised, dose-finding, multicenter study to determine the minimal effective dose and to assess the safety of r-hLH to support r-hFSH-induced follicular development in anovulatory women with hypogonadotropic hypogonadism in 40 number of subjects. • A Phase III multicenter, non-comparative study to evaluate the efficacy and safety of r-hLH to support r-hFSH-induced follicular development in LH and FSH deficient anovulatory women (WHO Group I) in 38 number of subjects. • A phase III multicenter study for the evaluation of the efficacy and safety of r-hLH to support r-hFSH induced follicular development in LH and FSH deficient anovulatory women (WHO group I) in 15 number of subjects. • A phase III, prospective, randomized, controlled, double-blind, multicenter study to confirm the efficacy and safety of r-hLH, 75 IU, administered subcutaneously, to support r-hFSH-induced follicular development in women with hypogonadotropic hypogonadism and severe LH deficiency who desire pregnancy in 39 number of subjects.
Decision: Keeping in view above; Registration Board after deliberation and legalized CoPP issued by EMA indicating product availability in European Union, Registration Board approved the product subject to compliance of current import policy for finished products.	

C. <u>Miscellaneous/Deferred Cases:</u>

25. Virtual GMP Inspection Report of M/s Virchow Biotech Private Limited India for Imported Human Biological (Rasburant 1.5mg/vial) by M/s Lab Diagnostic Systems (SMC) Pvt Ltd Rawalpindi.

Following biological product approved in 312th meeting of Registration Board subject to the inspection of manufacturer abroad as per import policy.

Name of Importer/ Manufacturer & meeting number	Name of Drug &Composition	Panel of Inspector(s)/ Date of inspection
M/s Lab Diagnostic Systems (SMC) Pvt Ltd Rawalpindi. **Manufacturer:** Virchow Biotech Private Limited, Survey No. 172 Parts, Gagillapur (V) Dundigal–Gandimaisamma (M), Medhchal–Malkajgiri (D), Telangana (State) – 500043, INDIA **(M-312).**	Rasburant 1.5mg/vial (Lyophilized Powder for Injection) Each vial contains; Rasburicase (r-DNA origin)…..1.5mg	i Mr. Muhammad Kashif, Deputy Director (BE&R) ii Mr. Abdullah Abro, Deputy Director (CD) **31-01-2023 and 11-04-2023**

Accordingly, an inspection was carried out by inspection panel dated 31-01-2023 & 1104-2023 and final remarks of the panel are as under: -

Recommendations of the panel:
Based on the proceedings of virtual inspection, documents reviewed and videos of the unit seen, and considering the fact it's a urate oxidase enzyme (no killed/attenuated organism in final product), the panel has come to the conclusion that the firm has adequate systems to manufacture **Rasburant** and appeared to comply the GMP requirements. Hence, the panel recommends the grant of registration of the applied product namely **Rasburant 1.5mg/vial (Lyophilized powder for injection)** to **M/s Lab Diagnostic Systems (SMC) Pvt. Ltd.**

However, the panel strongly recommends **on-site inspection** in order to verify/ascertain the Good Manufacturing Practices (GMP) of the firm **within one year** as virtual inspection can never replace physical/ in-person inspection.

Decision of RB in its 330th meeting:
Registration Board decided to refer back the case to the panel for clear and candid recommendations regarding registration of the product "Rasburant 1.5mg/vial (Lyophilized Powder for Injection)".

Remarks of evaluator:
The case was referred back to the panel as per decision of the Registration Board and the final remarks of the panel are as under;
"The panel has already recommended the grant of registration of the applied product namely Rasburant 1.5mg/vial (Lyophilized powder for injection) to M/s Lab Diagnostic Systems (SMC) Pvt. Ltd, based on the proceedings of virtual inspection, documents reviewed and videos of the unit seen, and considering the fact that it's a urate oxidase enzyme (no killed/ attenuated organism in final product).

Further, the panel has previously recommended on-site inspection in order to verify/ ascertain the Good Manufacturing Practices (GMP) of the firm within one year as virtual inspection can never replace physical/in-person inspection. The Board is requested that if the onsite inspection is not possible within one year then onsite inspection may be conducted at the time of renewal of registration or as deem fit by the Registration Board.

The Board is further apprised that the firm is facilitating for provision of Rasburicase 1.5 mg on NOC basis to Indus Hospital and Health Network, Karachi. They have imported 100 vials from April 2023 - till date."

Decision: Registration Board keeping in view recommendation of panel of experts advised the division to process the case for issuance of registration letter for 5 years as per law.

26. <u>Virtual GMP Inspection Report of Manufacturer Abroad (China) for Imported Human Biological (Enoxaparin Sodium)</u>

Following biological product of M/s Medi Mark Pharmaceuticals, Sahiwal was approved in 312th meeting of Registration Board subject to the inspection of manufacturer abroad as per import policy.

S.No.	Name of Importer/ Manufacturer & meeting number	Name of Drug &Composition	Panel of Inspector(s)/ Date of inspection
1.	M/s. Medi Mark Pharmaceuticals, Liaquat Chowk, Sahiwal. **Manufacturer:** M/s. Dongying Tiandong Pharmaceutical Co., Ltd China. **(M-312)**	1. Enoxaparin sodium **Careparin Injection PFS** Each 0.4ml dose contains; Enoxaparin sodium……4000 AXa IU 2. Enoxaparin sodium **Careparin Injection PFS** Each 0.4ml dose contains; Enoxaparin sodium……4000 AXa IU	i. Mr. Arif Chaudhary, Additional Director ii. Mr. Salateen Waseem Philip, Deputy Director **06-03-2023 &** **07-03-2023**

Accordingly, an inspection was carried out by inspection panel (mentioned above) dated 06-03-2023 & 07-03-2023 and final remarks of the panel are as under: -

Recommendations of the panel:

Based on visual remote inspection. documentation reviewed, Manufacture's export of enoxaparin to other countries & conversation with the manufacturing and quality control teams, the panel found the manufacturing unit operating at an acceptable level of compliance with GMP & recommends the grant of registration for import of following two (02) products for the period of one (01) year initially, subject to onsite inspection for grant of registration for period of five (05) years,

i.	Enoxaparin sodium **Careparin Injection PFS** Each 0.6ml dose contains; Enoxaparin sodium……6000 AXa IU
ii.	Enoxaparin sodium **Careparin Injection PFS** Each 0.4ml dose contains; Enoxaparin sodium……4000 AXa IU

Onsite inspection is highly recommended at the earliest to confirm source of Heparin from slaughterhouse along with transportation measures & confirmation of air flow patterns in line with movement of workers in the filling area of Enoxaparin Injections.

Decision of RB in its 331st meeting: Registration Board decided to refer back the case to the panel for clear and candid recommendations regarding registration of the product "Careparin Injection PFS".

Evaluation by DBER:

The clear and candid recommendations of the panel for virtual inspection of above mentioned biological drug products are as under;

"Based on visual remote inspection / remote interactive evaluation (RIE), on the basis of Good Reliance Practices recognizing the Manufacturer's export of these drug products to other countries (Philippines & South American Countries) including approval by The Brazilian Health Regulatory Agency (ANVISA), USFDA's consideration of API facility of the firm as minimally acceptable state of compliance with regard to cGMP (Annex-I), documentation reviewed, conversation with the manufacturing and quality control teams, the panel found the manufacturing unit operating at an acceptable level of compliance with GMP & therefore recommends the grant of following two (02) products

i- Careparin Injection PFS 0.6ml

ii- Careparin Injection PFS 0.4ml
Panel suggested to also plan an onsite audit of facility in future, before or at the time of renewal of drug product for more comprehensive perspective."

Decision: Registration Board keeping in view recommendation of panel of experts advised the division to process the case for issuance of registration letter for 5 years as per law.

Imported Veterinary Biological applied by M/s Vety Care (Pvt.) Ltd., deferred in 330th meeting of Registration Board

27.	**Name of Applicant**	**M/s Vety Care (Pvt.) Ltd.,** Plot #77, St#6, I-10/3, Islamabad.
	DSL details	DSL No.**156 ICT/2013** dated 31-12-2014 valid till 20-12-2022.
	Name of Manufacturer and Product License Holder:	**Product License Holder:** M/s Intervet Nederland B.V. Wim de Korverstraat 35 5831, AN Boxmeer, The Netherlands **Manufacturer:** M/s Intervet International B.V. Wim de Korverstraat 35 5831, AN Boxmeer, Netherland
	Name of exporting country	**Netherland**
	Brand Name +Dosage	**Nobilis Rismavac**
	Composition	Each dose contains: Live Chicken Herpes Virus, Strain CVI988……at least $3.0\log_{10}TCID_{50}$
	Finished Product Specifications	Ph. Eur. Specifications
	Pharmacological Group	Veterinary Vaccine
	Shelf life	60 months (Store in Liquid Nitrogen Container)
	Pack size & Demanded Price	**1000 doses Ampoule/** Decontrolled
	International Availability	Netherland
	Alternate Products already registered in Pakistan	Cevac MD Rispens (Reg. No. 077532)
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 17772 (R&I) Date: 15-01-2020 &24-06-2021 Rs. 100000/-
	General documentation	• Legalized COPP No. 258907 dated 01-03-2023
	Evaluation by DBER	i. Only Virus Titer has been performed in stability studies. The manufacturer has submitted that only virus titration might change during stability studies therefore only one test is performed. ii. The firm has applied for two pack sizes against one CoPP while pack sizes are not mentioned on CoPP. The firm was asked for evidence and the firm submitted that product is available in country of origin. iii. No. of doses/ pack is not mentioned in stability studies. iv. Stability study data provided is of only last time point.

	Decision of RB in 312th meeting	Registration Board deferred the product for submission of following by the firm: a. Stability data indicating pack size of the product including all parameters as mentioned in finished product specifications for appropriate time intervals i.e. 0, 3, 6, 9, 12, 18……..months. b. Valid Legalized CoPP indicating desired pack sizes as two different pack sizes are applied.
	Evaluation by DBER	1. The firm has now provided the stability data of 3 random batches of 2000 doses at following time intervals and only virus titration and identification tests are performed; Batch A2904: 0,9,15,21,27,33,35,42 months Batch A760A: 0,24,36,48,60 months Batch A8584: 0,12,24,36,48 months. However, stability data of 3 commercial batches of 1000 doses pack size, including all parameters as mentioned in Finished Product Specifications for appropriate time intervals, is still not provided. 2. Regarding CoPP, the firm informed that the COPP is on WHO approved format and pack sizes are not mentioned in COPP. The firm has submitted valid legalized COPP No. 258907 dated 1st March,2023.
	Decision of RB in 330th meeting	Deferred for submission of stability data of 03 commercial batches of applied pack size indicating all parameters as mentioned in Finished Product Specifications and on all time points as recommended by the European Union guidelines.
	Evaluation by DBER	The firm has provided the stability data of 3 commercial batches (Batch# A290A, A760A, A858A) at 0,3,6,9,12,18,24,36,48,60 months and titre, identity, sterility, safety, extraneous agents are tested at all these time points.
	Decision: Keeping in view above; Registration Board, after deliberation, legalized CoPP and product availability in the country of origin, approved the product subject to compliance to current import policy for finished drugs.	

Imported Veterinary Biological applied by M/s Vety Care (Pvt.) Ltd., deferred in 330th meeting of Registration Board

28.	**Name of Applicant**	**M/s Vety Care (Pvt.) Ltd.,** Plot #77, St#6, I-10/3, Islamabad.
	DSL details	DSL No.**156 ICT/2013** dated 31-12-2014 valid till 20-12-2022.
	Name of Manufacturer and Product License Holder:	**Product License Holder:** M/s Intervet Nederland B.V. Wim de Korverstraat 35 5831, AN Boxmeer, The Netherlands **Manufacturer:** M/s Intervet International B.V. Wim de Korverstraat 35 5831, AN Boxmeer, Netherland
	Name of exporting country	**Netherland**
	Brand Name +Dosage	**Nobilis Rismavac**
	Composition	Each dose contains: Live Chicken Herpes Virus, Strain CVI988……at least $3.0 \log_{10} TCID_{50}$
	Finished Product Specifications	Ph. Eur. Specifications

	Pharmacological Group	Veterinary Vaccine
	Shelf life	60 months (Store in Liquid Nitrogen Container)
	Pack size & Demanded Price	**2000 doses Ampoule/** Decontrolled
	International Availability	**Netherland**
	Alternate Products already registered in Pakistan	Cevac MD Rispens (Reg. No. 077532)
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 17772 (R&I) Date: 15-01-2020 &24-06-2021 Rs. 100000/-
	General documentation	• Legalized COPP No. 258907 dated 01-03-2023
	Evaluation by DBER	➢ Only Virus Titer has been performed in stability studies. The manufacturer has submitted that only virus titration might change during stability studies therefore only one test is performed. ➢ The firm has applied for two pack sizes against one CoPP while pack sizes are not mentioned on CoPP. The firm was asked for evidence and the firm submitted that product is available in country of origin. ➢ No. of doses/ pack is not mentioned in stability studies. ➢ Stability study data provided is of only last time point.
	Decision of RB in 312th meeting	Registration Board deferred the product for submission of following by the firm: a. Stability data indicating pack size of the product including all parameters as mentioned in finished product specifications for appropriate time intervals i.e. 0, 3, 6, 9, 12, 18…….months. b. Valid Legalized CoPP indicating desired pack sizes as two different pack sizes are applied.
	Evaluation by DBER	➢ The firm has now provided the stability data of 3 random batches of 2000 doses at following time intervals and only virus titration and identification tests are performed; Batch A2904: 0,9,15,21,27,33,35,42 months Batch A760A: 0,24,36,48,60 months Batch A8584: 0,12,24,36,48 months. However, stability data of 3 commercial batches of 1000 doses pack size, including all parameters as mentioned in Finished Product Specifications for appropriate time intervals, is still not provided. ➢ Regarding CoPP, the firm informed that the COPP is on WHO approved format and pack sizes are not mentioned in COPP. The firm has submitted valid legalized COPP No. 258907 dated 1st March,2023.
	Decision of RB in 330th meeting	Deferred for submission of stability data of 03 commercial batches of applied pack size indicating all parameters as mentioned in Finished Product Specifications and on all time points as recommended by the European Union guidelines.
	Evaluation by DBER	The firm has provided the stability data of 3 commercial batches (Batch# A290A, A760A, A858A) at 0,3,6,9,12,18,24,36,48,60 months and titre, identity, sterility, safety, extraneous agents are tested at all these time points.
	Decision: Keeping in view above; Registration Board, after deliberation, Legalized Free Sale certificate indicating product availability in country of origin, Legalized GMP Certificate and on	

	the recommendations of veterinary expert member Registration Board, approved the product subject to compliance to current import policy for finished drug.

Imported Veterinary Biological applied by M/s Vety Care (Pvt.) Ltd., deferred in 312th meeting of Registration Board

29.	**Name of Applicant**	**M/s Vety Care (Pvt.) Ltd.,** Plot #77, St#6, I-10/3, Islamabad.
	DSL details	DSL No.**156 ICT/2013** dated 31-12-2014 valid till 20-12-2022.
	Name of Manufacturer and Product License Holder	**Product License Holder:** M/s Intervet Nederland B.V. Wim de Korverstraat 35 5831, AN Boxmeer, The Netherlands **Manufacturer:** M/s Intervet International B.V. Wim de Korverstraat 35 5831, AN Boxmeer, Netherland
	Name of exporting country	**Netherland**
	Brand Name +Dosage	**Nobilis Rhino CV**
	Composition	Each ml contains: Live Attenuated Avian Rhinotracheitis Virus Strain TRT 11/94……at least $10^{1.5}TCID_{50}$ and max. $10^{3.7}TCID_{50}$
	Finished Product Specifications	As per Innovator's Specifications
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months ($2^{o}C$ - 8°C)
	Pack size & Demanded Price	1000 doses vial/ Decontrolled
	International Availability	Netherland
	Alternate Products already registered in Pakistan	Already registered product Hipraviar-SHS (Reg. No. 094781) contains 1062 strains.
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 17772 (R&I) Date: 03-03-2020 &24-06-2021 Rs. 100000/-
	General documentation	• Legalized COPP No. 251543 dated 11-06-2019
	Remarks of the Evaluator	i)Only two tests Titre & Residual Moisture have been performed in stability studies. The manufacturer has submitted that they only perform those tests in stability studies which influence the stability of the product and they don't have the data for all parameters. ii)Minimum dose as per composition is $10^{1.5}$ $TCID_{50}$ while in efficacy study $10^{2.5}$ $TCID_{50}$ and $10^{2.8}$ $TCID_{50}$ dose is used. The firm was asked for clarification whether at $10^{1.5}$ $TCID_{50}$ vaccine will be effective or not. The firm has not submitted the clarification.
	Decision of RB in 312th meeting	Registration Board deferred the product for submission of following by the firm: a. Stability data of the product including all parameters as mentioned in finished product specifications. b. Clarification, as the lower limit of strength of active ingredient is lower than the dose used in efficacy studies.

	Remarks of the Evaluator	a. The firm has submitted a statement from the manufacturer regarding stability studies wherein the manufacturer stated that only at T=0, (before the start of stability study) full QC tests are performed as per Finished product specification and according to EU guideline to GMP the following tests are considered as stability indicating and have to be performed during the stability study at each time point or at the end of shelf life: - Content test (titration): tested each time point during the stability study - Residual moisture test: enhanced moisture may affect the quality of the product and will be tested each time point during the stability study. **(However, VICH guidelines states that Stability studies should include testing of those attributes of the medicinal product that are susceptible to change during storage and are likely to influence quality, safety, and/or efficacy. The testing should cover, as appropriate, the physical, chemical, biological, and microbiological attributes, preservative content and functionality tests).** b. The firm has also submitted a clarification from manufacturer that following studies were performed with Nobilis Rhino CV at doses $10^{1.5}$ $TCID_{50}$ per animal or even lower. • Study: TRT/96/AVR/156: three inocula: $10^{3.5}$, $10^{2.5}$ or $10^{1.5}$ TCID50 per animal protective levels were seen at inoculum doses down to $10^{1.5}$ $TCID_{50}$/Chick. • Study: TRT/96/AVR/162: $10^{1.5}$, < $10^{0.7}$ (>> $10^{0.5}$) OR << $10^{0.7}$ (>> $10^{0.05}$) TCID50 per animal (inoculum doses were about 30-fold lower than intended). • Conclusion: Upon coarse spray application of Nobilis RTCV 1194 vaccine to day-old chicks with high leverls of maternally derived immunity, protective immunity was induced resulting in a highly statistically significant reduction or clinical sign causd by challenge virus infection, both at 3 and at 6 weeks post-vaccination. Best protective levels were seen at an inoculum dose of $10^{1.5}$ $TCID_{50}$/ chick. • Study: TRT/97/AVR/177: three inocula: $10^{3.1}$, $10^{2.0}$, or $10^{1.2}$, $TCID_{50}$ per animal. • Conclusion: Upon coarse spray application of Nobilis RTCV 11494 vaccine to day-old chicks with high levels of maternally derived immunity, protective immunity was induced resulting in a highly statistically significant reduction of clinical sign caused by challenge virus infection at 3, 6 and 16 weeks post-vaccination. Excellent protective levels were seen at an inoculum dose down to $10^{1.2}$ $TCID_{50}$/ chick. • Study: TRT/03R/AVR/244: Nobilis TRCV 1194: $10^{1.5}$ TCID50/ animal by oculonasal route. Conclusion: The results show that vaccination of MDA positive birds with a minimum dose of 1.5 log10 TCID50 provide full protection against a heterologous challenge from about 1 week of age onwards up to 7 weeks after vaccination.
	Decision: Keeping in view above; Registration Board, after deliberation, Legalized Free Sale certificate indicating product availability in country of origin, Legalized GMP Certificate and on the recommendations of veterinary expert member Registration Board, approved the product subject to compliance to current import policy for finished drug.	

Imported Veterinary Biological applied by M/s Hilton Pharma (Pvt.) Ltd., deferred in 312th meeting of Registration Board

30.	Name of Importer	M/s Hilton Pharma (Pvt.) Ltd. Plot 13-14 & 43, Sector 15, Korangi Industrial Area Karachi.
	DSL details	License to sell drug as distributor valid till 19-Jun-2024
	Name of Manufacturer	M/s PT. Medion Farma Jaya Address: Office: JI. Babakan Ciparay No. 282, Babakan Ciparay, Bandung-Indonesia. Plant: JI. Raya Batujajar No. 29, Cimareme, Ngamprah, Bandung Barat-Indonesia.
	Name of exporting country	**Indonesia**
	Brand Name + Dosage Form + Strength	**Medivac Gumboro A vaccine** Freeze dried live vaccine
	Diary No. Date of R& I & fee	Dy No. 26809 Dated: 12-10-2020, Dy No. 29865 dated 1211-2021 Fee Submitted: Rs. 50,000/- & Rs. 50,000/- dated 5-10-2020, 12-11-2021.
	Composition	Each dose of vaccine contains: Infectious bursal disease (IBD) Virus, live vaccine, Cheville (1/68) strain .....$>10^{2.0}EID_{50}$.
	Pharmacological Group	Freeze dried live vaccine against infectious bursal disease / Gumboro disease in poultry
	Type of Form	Form-5A
	Finished Product Specification	Ph. Eur. Specifications
	Shelf Life	24 Months (2°C - 8°C)
	Pack size and demanded price	1000 dose vial / Decontrolled
	Products already registered in Pakistan	IBA Vac of M/s Forward Solutions.
	Stability data of finished product	Firm has submitted the stability data. Medivac Gumboro A (1000 doses) for 24 months stored at 2-8 °C. Batch No. 88B093, 88B094 and 88B095.
	Document Details	Legalized Certificate of Pharmaceutical Product (CoPP) No 18023/PI.500/F/10/2019 dated October 18,2018 issued by: Ministry of Agriculture Directorate General of livestock and animal health services Indonesia.

Previous Decision: Registration Board deferred the product for submission of Scientific literature confirming Immunological relevance of applied strain with circulating strain of Pakistan **(M-313)**

Evaluation by BE&R:

The firm has submitted the scientific literature reference and summary is as follow.

- The re-emergence of virulent strains of the Infectious Bursal Disease Virus (IBDV) leads to significant economic losses of poultry industry in Pakistan during last few years. This disease causes the infection of bursa, which leads to major immune losses.
- Among all the outbreaks, almost 80% of poultry birds were found positive for the IBDV.
- The findings indicated the molecular features of the Pakistan IBDV strains playing a role in the evolution of new strains.
- Only Serotype-I is known to cause disease in birds.

- The economic losses due to IBD experienced by the poultry industry are not only the result of mortality and morbidity but the dramatic fall in the overall performance of the flock.
- IBD results in the economic impacts on the layer and broiler chicken industry that is estimated to be 3.9 million kilograms of meat per year having $14 million market value.
- There is no treatment for this disease, but vaccination and biosecurity.
- Our study aimed to identify IBDV strains that continue to affect and cause disease in commercial chicken flocks.
- All the four Pakistan strains were submitted to GenBank, and the accession numbers are listed Table.
- Among the viral diseases of the poultry flocks, IBDV is the second foremost disease after Newcastle disease.
- In the current study, the Infectious Bursal Disease Virus isolates were found to be present in genogroup 1, genogroup 4, and genogroup 5. All three genogroups are prevalent globally while the re-assorted and mutated isolated were confined to the specific regions of the world.

Decision of RB in its 331st meeting:	Registration Board deferred the case for submission of scientific justification for immunological relevance of applied strain with circulating strain of Pakistan.
Evaluation by BE&R:	Firm has submitted response via letter no. SA/MN/01032024 on dated 1st March 2024, summary is as follow. The Medivac Gumboro A Vaccine contains strain of Infectious Bursal Disease (IBD) virus Cheville (1/68) at least $10^{2.0}EID_{50}$ which is actually renamed of IBD virus of Winterfield 2512 Strain. The manufacturer obtained the master seed of IBD virus strain Winterfield 2512 from Cen Veterinary Laboratory Weybridge, Surrey, England (Attenuated by Dr. Roland Winterfield). Further PT Medion Farma Jaya renamed the master seed with internal company name called **Cheville (l/68),** invoice/evidence submitted . The firm submitted the status of Medivac Gumboro A in exporting countries as below:

No	Brand Name	Country	Reg. No	Validity
1	Medivac Gumboro A	Vietnam	MDI-11	April 2027
2	Medivac Gumboro A	West Malaysia	TACB 38/07	July 2026
3	Medivac Gumboro A	East Malaysia	(9)DVS/HQ/700-3/1/6	December 2024
4	Medivac Gumboro A	Cambodia	FR02-003-1496/0520 BKP-GDAHP	May 2025
5	Medivac Gumboro A	Singapore	Registered-04 Juni 2018	October 2028

Firm has also submitted the local registration evidence for Winterfield 2512 Strain, such as PoulShot® IBD win, IBA-VAC ST, and Avi IBD Plus.

Decision: Keeping in view above; Registration Board, after deliberation, Legalized Free Sale certificate indicating product availability in country of origin, Legalized GMP Certificate and on the recommendations of veterinary expert member Registration Board, approved the product subject to compliance to current import policy for finished drug.

Imported Veterinary Biological applied by M/s Saadat International, deferred in 331st meeting of Registration Board

31.	**Name and address of Importer**	**M/s Saadat International** 117-Habitat Apartments, Shadman-II, Jail Road, Lahore
	Detail of DSL	M/s Saadat International Address: 117 Habitat Apartments Shadman II, Jail Road, Lahore. Valid till: 24-Feb-2028
	Name and address of Manufacturer and MAH	**Marketing Authorization Holder:** Name: Boehringer Ingelheim Vetmedica GmbH Address: Binger Straße 173, 55216 Ingelheim am Rhein, Germany **Manufacturer:** Name: Boehringer Ingelheim Vetmedica, S.A. de C.V. Address: Calle 30 No. 2614, Zona Industrial, C.P. 44940 Guadalajara, Jalisco, Mexico.
	Name of exporting country	**Mexico.**
	Brand Name +Dosage Form + Strength	**VOLVAC BEST AI + ND**
	Diary No. Date of R& I & fee	Dy. No. 10583 R&I Dated 27-04-2022 Rs. 150,000/- (Slip No. 51647879232)
	Composition Each dose contains:	Each dose (0.5 mL) contains: Inactivated subunit H5 Hemagglutinin (HA) of High Pathogenic Avian Influenza (HPAI) virus H5N1, atleast……..…..256 HAU Newcastle Disease Virus, LaSota strain, at least..……..128 HAU (HAU: Haemagglutination units)
	Pharmacological Group	Immunological, QI01AA23 & QI01AA02.
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specifications
	Shelf Life	24 months (2°C-7°C)
	Document Details	Legalized COPP (No. BOO.02.01.02.02.0336-2021) dated 04-FEB-2021 issued by General Bureau of Animal Health, Directorate for Livestock & Services and Certification is submitted by the firm. (COPP shows that the product is not on Free Sale in Country of origin and the product is registered for export purpose only)
	Pack size	**1000doses/500ml**
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	Noblis Influenza H5N2 (manufacturer: MSD Animal Health) importer: Vety Care, Islamabad Avian Influenza Virus Vaccine H5N2 (manufacturer: QYH BIOTECH) importer: VET LINE International, Lahore IZOVAC AVIFLU H5N2 (manufacturer: Vaxxinova) importer: Ghazi Brothers, Karachi (All the above-mentioned vaccines are having H5N2 strain while the applied product is H5N1).
	Remarks of Evaluator	• **MAH in COPP**: Boehringer Ingelheim Vetmedica, S.A. de C.V. Calle 30 No. 2614, Zona Industrial, C.P. 44940 Guadalajara, Jalisco, Mexico. **MAH mentioned in Form-5A**: Boehringer Ingelheim Vetmedica GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Germany. • The product is not on free sale in country of origin (Mexico) and the COPP is for export purpose only.

		• The applied strain (H5N1) is not registered in Pakistan as per available record.
	Decision of RB in its 331st meeting	Registration Board deferred the case for submission of registration free sale in the country of origin, clarification of MAH and International availability of applied strain.
	Evaluation by BE&R	The firm has submitted the following. • Legalized Free Sale Certificate issued by General Bureau of Animal Health, Directorate for the Regulation of Establishments, Products and Contributing Bodies dated 05-09-2023 showing the product is freely marketed in the Mexican Republic with the Brand name "VOLVAC B.E.S.T. AI+ND KV" while the Brand Name for Export purpose is "VOLVAC B.E.S.T. AI+ ND". • Legalized GMP Certificate No.R.06/2021 dated 26-11-2021 valid till 20-12-2024. • Regarding MAH, the firm submitted that. "The MAH mentioned in the CPP is the manufacturer—this is the MAH in the country of origin or the manufacturer country (Mexico), however the MAH globally is the headquarter Boehringer Ingelheim Gmbh, Germany as mentioned in the application." • Regarding International availability of applied strain, the firm has submitted articles of different journals wherein international availability of applied strain is not confirmed.
Decision: Keeping in view above; Registration Board, after deliberation, Legalized Free Sale certificate indicating product availability in country of origin, Legalized GMP Certificate and on the recommendations of veterinary expert member Registration Board, approved the product subject to compliance to current import policy for finished drug.		

AGENDA FOR EXPORT AND BULK IMPORT LOCAL REPACK FOR EXPORT PURPOSE

Case No.32: Registration of Drug (s) of M/s Macter International Ltd., F-216, S.I.T.E., Karachi for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 2-13/95-Lic (Vol-IV) dated 19-07-2012
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate dated 04-08-2022.
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	**II**	**III**	**IV**
1.	Seglutide 4mg/3mL Solution for Injection Each multi-dose vial contains:	Vial Packaging is not registered.	Dy. No. 4862 (20.02.2023) Rs.30, 000/- 02.02.2023) Rs. 45,000/- (24-04-2024)

	Semaglutide…….4mg		
2.	Seglutide 2mg/1.5mL Solution for Injection Each multi-dose vial contains: Semaglutide…….2mg	Vial Packaging is not registered.	Dy. No. 4861 (20.02.2023) Rs.30, 000/- 02.02.2023) Rs. 45,000/- (24-04-2024)
Source: M/s Livzon New North River Pharmaceutical Co., Ltd. Renmin One Road, Qingyuan City, Guangdong Province, China.			

Remarks:

i. The submitted copy of GMP Certificate is issued by Qingyuan City Qingcheng District Shijiao Tow Industrial Park Management Committee, Qingyuan City, China.

ii. Copy of Export Order from M/s Shahnawaz Enterprises, Afghanistan is submitted.

Decision: The Board after detailed deliberation approved the products Seglutide 4mg/3mL and Seglutide 2mg/1.5mL for export purposes only.

Case No.33: Registration of Drug (s) of M/s BF Biosciences Ltd., 5-Km, Sunder Raiwind Road, Raiwind, Lahore for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from Panel Inspection Report dated 01-03-2022
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate dated 06-07-2021.
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy. No. (EFD)/Fee with date
I	**II**	**III**	**IV**
1.	Sematide 0.25mg Injection Solution for Injection in PFS Each 0.188mL contains: Semaglutide…….0.25mg	Not Available	Dy. No. 17967 (17.07.2023) Rs.30, 000/- 07-.07.2023) Rs. 45,000/- (23-04-2024)
2.	Sematide 0.5mg Injection Solution for Injection in PFS Each 0.375mL contains: Semaglutide…….0.5mg	Not Available	Dy. No. 17968 (17.07.2023) Rs.30, 000/- 07-.07.2023) Rs. 45,000/- (23-04-2024)
3.	Sematide 1mg Injection Solution for Injection in PFS Each 0.75mL contains: Semaglutide…….1mg	Not Available	Dy. No. 17969 (17.07.2023) Rs.30, 000/- 07-.07.2023) Rs. 45,000/- (23-04-2024)
Source of Bulk: M/s Zhejiang Peptites Biotech Co., Ltd., No. 8, Hengyizhi rd, Sanjie town, Shengzhou, Zhejiang, China.			

Remarks:

i. The submitted copy of GMP Certificate is issued by China National Association of Pharmaceutical and Medical Equipment Industry Technical Market, China.

ii. Copy of Export Order from M/s Haroon Zazai Ltd., Afghanistan is submitted.

Decision: The Board after detailed deliberation approved the products Sematide 0.25mg Injection, Sematide 0.5mg Injection and Sematide 1mg Injection for export purposes only.

Case No.34: Registration of Drug (s) of M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II, Industrial Area, Hatter for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML along with evidence of DML renewal application is provided Approval of relevant section verified from Licensing Division Letter No. F. 3-6/2007-Lic (Vol-II) dated 25-10-2023.
GMP Status. Copy of Inspection report/GMP certificate.	New Section is approved on 25-10-2023
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy. No. (EFD)/Fee with date
I	**II**	**III**	**IV**
1.	Semggo 3mg Tablet Each uncoated tablet contains: Semaglutide…….3mg	Rybelsus of Novo Nordisk	Dy. No. 1703 (08.12.2023) Rs.30, 000/- 15.11.2023)
2.	Semggo 7mg Tablet Each uncoated tablet contains: Semaglutide…….7mg	Rybelsus of Novo Nordisk	Dy. No. 1704 (08.12.2023) Rs.30, 000/- 15.11.2023
3.	Semggo 14mg Tablet Each uncoated tablet contains: Semaglutide…….7mg	Rybelsus of Novo Nordisk	Dy. No. 1702 (08.12.2023) Rs.30, 000/- 15.11.2023

Remarks:

The case was evaluated and the deficiency letter has been issued with following requirements for which the firm has responded till yet:

- **i.** Valid GMP certificate of Source of API is required.
- **ii.** Manufacturing process and Analytical procedures of Semaglutide (API) is required as it is a biological product.
- **iii.** Salcaprozate sodium is used in the formulation which is a novel excipient. So, details regarding its manufacturer, process and method validations and certificate of analysis is required.
- **iv.** Complete descriptions of the specifications and analytical methods of the Finished product is required including test for assay of Salcaprozate sodium in semaglutide tablet.
- **v.** Form 5 is a part of Drugs (Licensing, Registering and Advertising) Rules, 1976 and its format and title cannot be changed. So properly filled and signed Form 5 is required in its actual format.
- **vi.** The brand name mentioned on affidavit of SEMGGO 14mg Tablet is incorrect.
- **vii.** The fee challans of all three products are paid under the head of Pharmaceutical Evaluation and Registration while these are biological products.

Decision: The Board after detailed deliberation decided to defer the applications for submission of required documents.

Case No.35: Registration of Drug (s) of M/s Wnsfeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar manufactured by M/s Weather Folds Pharmaceuticals, Plot

No. 69/2, Phase-II, Industrial Area, Hatter on contract manufacturing for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML along with evidence of DML renewal application is provided Approval of relevant section of M/s Weather Folds verified from Licensing Division Letter No. F. 3-6/2007-Lic (Vol-II) dated 25-10-2023.
GMP Status. Copy of Inspection report/GMP certificate.	New Section is approved on 25-10-2023
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy. No. (EFD)/Fee with date
I	**II**	**III**	**IV**
1.	Maglu 3mg Tablet Each uncoated tablet contains: Semaglutide…….3mg	Rybelsus of Novo Nordisk	Dy. No. 1701 (08.12.2023) Rs.30, 000/- 15.11.2023)
2.	Maglu 7mg Tablet Each uncoated tablet contains: Semaglutide…….7mg	Rybelsus of Novo Nordisk	Dy. No. 1700 (08.12.2023) Rs.30, 000/- 15.11.2023
3.	Maglu 7mg Tablet Each uncoated tablet contains: Semaglutide…….7mg	Rybelsus of Novo Nordisk	Dy. No. 1699 (08.12.2023) Rs.30, 000/- 15.11.2023

Remarks:

The case was evaluated and the deficiency letter has been issued with following requirements for which the firm has responded till yet:

- **i.** Contract/Agreement with M/s Weather Folds for Toll manufacturing is not provided.
- **ii.** Valid GMP certificate of Source of API is required.
- **iii.** Manufacturing process and Analytical procedures of Semaglutide (API) is required as it is a biological product.
- **iv.** Salcaprozate sodium is used in the formulation which is a novel excipient. So, details regarding its manufacturer, process and method validations and certificate of analysis is required.
- **v.** Complete descriptions of the specifications and analytical methods of the Finished product is required including test for assay of Salcaprozate sodium in semaglutide tablet.
- **vi.** Form 5 is a part of Drugs (Licensing, Registering and Advertising) Rules, 1976 and its format and title cannot be changed. So properly filled and signed Form 5 is required in its actual format.
- **vii.** The brand name mentioned on affidavit of MEGLU 14mg Tablet is incorrect.
- **viii.** The fee challans of all three products are paid under the head of Pharmaceutical Evaluation and Registration while these are biological products.

Decision: The Board after detailed deliberation decided to defer the applications for submission of required documents.

Case No.36: Registration of Drug (s) of M/s Macter International Ltd., F-216, S.I.T.E., Karachi for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;

Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 2-13/95-Lic (Vol-IV) dated 19-07-2012
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate dated 04-08-2022.
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	**II**	**III**	**IV**
1.	Hepanox 10,000 IU/ 1.0mL Solution for Injection Each vial contains: Enoxaparin Sodium……100mg/1.0mL (1000 IU of Anti-Xa activity)	Clotenox 100mg of M/s Nextar	Dy. No.58 (02-01-2024) Rs.30,000/- (07-01-2024)
2.	Hepanox 8,000 IU/ 0.8mL Solution for Injection Each vial contains: Enoxaparin Sodium……80mg/0.8mL (8000IU of Anti-Xa activity)	Enoxaparin sodium PFS 8000IU/0.8mL by M/s Bio Medics Medical system	Dy. No.59 (02-01-2024) Rs.30,000/- (07-01-2024)
3.	Hepanox 6,000 IU/0.6mL Solution for Injection Each vial contains: Enoxaparin Sodium……60mg/0.6mL (6000IU of Anti-Xa activity)	Enoxaparin sodium PFS 6000IU/0.6mL by M/s Bio Medics Medical system	Dy. No.55 (02-01-2024) Rs.30,000/- (07-01-2024)
4.	Hepanox 4,000 IU/0.4mL Solution for Injection Each vial contains: Enoxaparin Sodium……40mg/0.4mL (4000IU of Anti-Xa activity)	Enoxaparin sodium PFS 4000IU/0.4mL by M/s Bio Medics Medical system	Dy. No.56 (02-01-2024) Rs.30,000/- (07-01-2024)
5.	Hepanox 2000 (20mg/0.2mL) Solution for Injection Each vial contains: Enoxaparin Sodium…….20mg (2000 IU of Anti-Xa activity)	Enoxaparin sodium PFS 2000IU/0.2mL by M/s Bio Medics Medical system	Dy. No.57 (02-01-2024) Rs.30,000/- (07-01-2024)
Source: Hubei Enoray Biopharmaceutical Co., Ltd No. 108 Yanjiang Road, Xiochi Town, Huangmei County Hubei Province China.			

Remarks:

i. The firm has submitted copy of CoPP of Heparin Sodium API of above bulk manufacturer valid till 08-11-2025 issued by Hubei Medical Products Administration, China.

Decision: The Board after detailed deliberation approved the products Hepanox 10,000 IU/ 1.0mL, Hepanox 8,000 IU/ 0.8mL , Hepanox 6,000 IU/0.6mL , Hepanox 4,000 IU/0.4mL and Hepanox 2000 (20mg/0.2mL) for export purposes only.

Case No.37: Registration of Drug (s) of M/s Getz Pharma Pvt Ltd., 29-30/27, Korangi Industrial Area, Karachi for export purposes only.

M/s Getz Pharma will **bulk import labelled vials** of Adalimab (Adalimumab) solution for Injection 40mg/0.8mL from M/s Shanghai Henlius Biopharmaceuticals Co., Ltd., situated at Building 1

(Building D), No.1289 Yishan Road, shanghai, China **for local repacking** at Getz Pharma (Pvt) Limited facility situated at Plot No.29-30, Sector 27, Korangi Industrial Area, Karachi:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided The firm will import bulk labelled vials and repack locally.
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate dated 17-01-2022.
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	**II**	**III**	**IV**
1.	ADALIMAB 40mg/0.8mL Solution for Injection in vials Each vial contains: Adalimumab…….40mg	*USFDA*	Dy. No.7894 (20-03-2023) Rs.75, 000/- (01-03-2023)
The firm has provided CoPP vide No. 20220086 issued by Shanghai Municipal Medical Products Administration Shanghai China which indicates that Adalimumab Injection 40mg is licensed and available on mallet in China. The firm has also submitted **Eudra GMP** for M/s Shanghai Henlius Biopharmaceuticals Co., Ltd., situated at Building D, No.1289 Yishan Road, shanghai, China.			

Remarks:

i. NOC from labelled vials manufacturer is required for re-export of products to other countries.
ii. Evidence of availability of facility for re-packing of products at 2-8^{0}C.

Decision: The Board after detailed deliberation on the application that there is no such provision under DRAP Act, 2012 in which labelled vials can be imported and after repacking it can be exported hence it is a policy decision. The Board decided to refer the case to the DRAP Authority.

Case No.38: Imported Veterinary Biological applied by M/s Orion Group, Faisalabad deferred in 334th meeting of RB.

Priority /Out of que Consideration on the basis of MOU signed between Sindh Govt. and manufacturer Dollvet.Turkey and Copy of Letter From Sindh Institute of Animal Health Live stock and Fisheries Department .Govt. of Sindh Adressing CEO DRAP requesting on priority approval of the FMD Vaccine to M/s Orion Group

1	**Name of Importer**	M/s Orion Group address P-79, Usman Block, Muslim Town No. 1, Near Lasani Pully, Sargodha Road, Faisalabad
	DSL details	M/s Orion Group address 79 Commercial Area , Usman Block, Muslim Town No. 01, Sargodha Road, Faisalabad DSL 06-331-0167-022405D,valid till . 20 –November 2023
	Name of Manufacturer	Product License Holder & Manufacturer M/s DOLLVET Biyotechnology A.S. Konaklar Mah. Akasyali Sok. No.10, Besiktas/ Istambul, Turkey Production Site:Kocoren OSB Mahallesi 106.Cadde No:6 Eyyubiya/Sanliurfa
	Brand Name + Dosage Form + Strength	AFTODOLL-JEL Suspension for Injection Inactivated viral vaccine
	Composition	Each dose of vaccine (2 ml) are as follows: **Active Ingredients**** O (PanaAsia-2)) ……..…… ≥ 6 PD50* A (Iran-05) ……..... ≥ 6 PD50*

		ASIA-1 (Sindh-08)……. ≥ 6 PD50* * PD50 – 50% bovine protective dose according to European Pharmacopoeia 0063 The number and type of vaccine strains included in the final product will be determined according to the epidemiological situation of the country/region and indicated on the label **Excipients** Aluminum hydroxide (Al+3)……. … 1.0 mg/ml Saponin…… 1.5 mg/ml
	Finished product specifications	Ph.Eur Specifications
	Pharmacological Group	Biological Inactivated Viral Veterinary vaccine
	Shelf life	18 months 2-8 ^{O}C
	International availability	Not Submitted
	Products already registered in Pakistan	Foot and mouth Disease Vaccine manufactured by FGBI Arriah Russia, Reg. No.052400, importer Mustafa Brothers
	Type of Form, Dy. No. Date of Application, Fee submitted	Form5-ADy. No.413 Date:23-01-2024 Fee Submitted: Rs150,000, Dated: 28-01-2024
	Demanded Price / Pack size	Decontrollered for Veterinary products/ 50ml bottle
	General Documentation	• Original Legalized CoPP valid till 25-11-2025 which also specifies the free sale of the product in countryof origin, GMP certificate and Product Agent Agreement and Power of Attorney are submitted • Copy of MOU Between Sindh Govt. and manufacturer Dollvet.Turkey • Copy of Letter From Sindh Institute of Animal Health Live stock and Fisheries Department Govt. of Sindh Adressing CEO DRAP requesting on priority .approval of .the FMD Vaccine to M/s Orion Group
	Remarks of BE&R	Additional fee of Rs.1,50,000/- is required to be submitted.
	Decision of 334th R.B Meeting: The Board deliberated on the letter of SIAH, Sindh stating that product shall be imported in Bulk and diluted in the premises of SIAH. Keeping in view the Board deferred the case for clarification whether the product will imported in finished form or as bulk import and local repack.	
	Response of the firm: Now the firm has submitted a copy of letter from the Executive Director SIAH stating the following: **"**It is submitted that the Sindh Institute of Animal Health, Karachi working under Livestock & Fisheries Department, government of Sindh has entered into an agreement and MOU with Dollvet turkey for the transfer of the technology and research in various vaccines and biologics, among them Foot & Mouth Disease (FMD) is one of them. The FMD is very much prevalent in Pakistan and hampering the process of export of livestock products, so therefore it's of a national importance to have a quality FMD vaccine. However, the cost of FMD vaccine production is very high so it's quite difficult to farmer to vaccinate their animal against the FMD disease due to higher price. The Sindh Institute of Animal health has collaborated with Dollvet Turkey to important high quality and cost efficient FMD vaccine. M/s Orion Group has already procured various vaccines i.e. PPR vaccine and some other vaccines from the above mentioned Turkish manufacturer and are satisfied with the quality of their vaccines which are also already registered with DRAP. Therefore, it is requested to your kind authority to please register the said FMD vaccine (Aftodoll-Jel) to M/s Orion Group for smooth availability of FMD vaccine on cheaper rates in the country in the best interest of the farmers of the country and nation at large.**"** The firm has also submitted differential fee of Rs. 150,000/-.	
Decision:	**Keeping in view of the letter of Sindh Institute of Animal Health, Karachi, the legalized CoPP indicating product availability in the country of origin, Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.**	

Case. 39 Delegation of Functions:

Registration Board, in its various meetings (262.276,277.284,288,290,292,295,296,297,307 316 and 333) has authorized its Chairman for certain functions, under Rule 24(10) of Drugs (Licensing, Registering & Advertising) Rules, 1976, which may be delegated to the Director BE&R, Division for Biological Products in order to facilitate timely disposal of various cases / post- registration variation cases/ contravention of various provisions of the Drugs Act, 1976.

Following functions are here by reframed and compiled as follows:

Sr. No.	Functions
1.	Change of name of the manufacturer of imported drug(s), where site remain same.
2.	Change of name/Address of the Marketing Authorization Holder of imported drug(s)
3.	Change of name/Address of the Importer of imported drug(s)
4.	Increase/ decrease in shelf life of registered drug.
5.	Action initiated on safety of drugs.
6.	Change in labeled storage conditions of imported product
7.	Change of source of bulk concentrate etc. of registered Biologicals.
8.	Change/correction of finished product specifications
9.	Issuance of show cause notice for cancellation of registration after cancellation of DML

Decision: Registration Board after detailed deliberation delegated above mentioned functions to Director Biological Evaluation and Research Division being a member of Registration Board under Rule 24(10) of Drugs (Licensing, Registering & Advertising) Rules, 1976.

Item No. IV. Division of Quality Assurance & Lab Testing

S. NO.	CASE TITLE
1.	RECALL OF PHARMIX PRODUCTS DUE TO PRESENCE OF IMPURITIES
2.	SUBSTANDARD MULTIVITAMIN SYRUP B. NO. J19:081 MANUFACTURED BY M/S. NAWABSONS LABORATORIES, JIA BAGGA OFF RAIWIND ROAD, LAHORE – QCB ISLAMABAD CASE
3.	SUBSTANDARD MENTIN FORTE TABLET MANUFACTURED BY M/S. UNEXO LABS LAHORE – QCB ISLAMABAD CASE
4.	MANUFACTURING AND SELLING 12922 PACKS OF NAZE 10ML DROPS BY M/S SCHAZOO PHARMACEUTICAL LABORATORIES (PVT) LTD WITHOUT APPROVED LIQUID (PSYCHOTROPIC) SECTION

Case No. 01: RECALL OF PHARMIX PRODUCTS DUE TO PRESENCE OF IMPURITIES

01. Incidents and Substandard/Falsified Medical Products (ISF), Regulation and Safety unit, World Health Organization informed regarding the identification of DEG/EG (via TLC testing) by Maldives Food and Drug Authority, Ministry of Health, Republic of Maldives (the sample was forwarded to TGA Australia for detailed testing via GC-FID analysis) in product namely Alergo Syrup Batch No. B220 (Mfg. Date: 16-02-2022 Exp. Date: 15-02-2024) manufactured and exported to Maldives by M/s. Pharmix Laboratories Lahore.

02. Subsequently, a panel of inspectors from DRAP Lahore office comprising of Mr. Abdul Rashid Shaikh, FID Lahore and Mr. Ishtiaq Shafiq Assistant Director, Lahore inspected the premised of M/s. Pharmix Laboratories Lahore on 10-11-2023.

03. Summary of the said report is given as under:

- In response to the information received from WHO, the panel inspected the firm on 10-11-2023. The panel has informed that M/s. Pharmix Laboratories Lahore had manufacturer batch No. B220 (Batch size 600L) of their product Alergo Syrup on 16-02-2022. The said batch contained sorbitol solution 70%, glycerin, and propylene glycol in its master formulation.
- The firm distributed the batch in Maldives (3000 packs), Laos (5000 packs), Belize (200 packs) Fiji (300 packs) and 400 packs locally in Pakistan. Firm has provided the details of NOC obtained from DRAP Lahore as Annex-A.
- Firm has provided details of the source of suspected excipients as under and has provided COAs of same:

S. No.	Name of Material	Name of Manufacturer
01	Sorbitol Solution 70%	PT Sorini As a Corporindo, Indonesia
02	Glycerin	PT Musim Mas Indonesia
03	Propylene Glycol	Dow chemical Pacific(Singapore)

- During inspection it was observed by the panel that in certificate of analysis, principle manufacturer has performed the impurity testing in the purported raw material of glycerin and propylene glycol. However, impurity testing was missing in the COA of the Sorbitol. Moreover, firm has not performed the impurities testing in-house or through a third party. It was also revealed that firm has same source of propylene glycol and glycerin (firm provided the report of third- party impurities testing conducted in 2023). However, firm has changed the source of sorbitol in December 2022
- Panel directed the firm to recall the batches of products containing the suspected excipients and took following samples as a part of risk-based approach for the purpose of test/analysis and directed the firm to stop the production of all oral liquid dosage forms and also hold available products and raw material in their warehouse till the finalization of results. In compliance to the directions firm has submitted an undertaking.

04. The panel further informed that M/s. Pharmix Laboratories Lahore has manufactured following products from the suspected contaminated batches:

S#	Product Name	Batch No.	Mfg. by
01.	Mucorid Syrup	A230, B201, B224, B225, C210, C227, L111, L121, A210, A211, A212, A230, B201	M/s. Pharmix Laboratories (Pvt.) Ltd., 21-Km Ferozpur Road, Lahore.
02.	Ulcofin Suspension	B209, C223	-do-
03.	Alergo syrup	B220, L126	-do-
04.	Emidone Suspension	B227	-do-
05.	Zincell Syrup	C218	-do-

05. In the light of above-mentioned inspection report, the division of QA&LT issued directions to M/s. Pharmix Laboratories Lahore to recall the products from both National and International Markets, issued Public notice on DRAP's website and informed the Regulatory Agencies of importing countries to recall the suspected products from their markets as well. Moreover, DRAP Karachi was also directed to inspect the suppliers of raw materials. DRAP Karachi team visited premises of M/s. United Chemicals Karachi (Supplier of Sorbitol) and M/s. Brother Enterprises Karachi (supplier of Propylene Glycol and Glycerin) and took samples of available raw materials from the later and forwarded the samples to CDL Karachi for the purpose of test/analysis. CDL Karachi vide report RM-11-23-000230 dated 21-12-2023 and RM-11-23-000231 dated 19-12-2023. Details of reports are as under:

S#	Raw material	B. No.	Mfg. by	Test	Result
01	Propylene Glycol	C815N4HR41		Ethylene Glycol	Not detected

			M/s. Dow Chemicals, Thailand.	Diethylene Glycol	Not detected
02	Glycerin 99.7% USP	000243IMD3C5L	M/s. PT Musim Mas Indonesia	Ethylene Glycol	Not detected
				Diethylene Glycol	Not detected

06. Details of CDL test/analysis reports of samples sent by the inspection panel of Lahore office from the premises of M/s. Pharmix Laboratories Lahore are given as under:

S#	Product name	Mfg. by	B. No.	CDL Report No.	Results
01	Allergo Syrup 120ml	M/s. Pharmix Laboratories (Pvt.) Ltd., Pakistan	L210	LHR-11-23-000038	EG content: 1.1116% DEG content: 0.1584%
02	-do-	-do-	B220	LHR-11-23-000026	EG content: 0.8874 % DEG content: 0.1087%
03	-do-	-do-	H231	LHR-11-23-000053	EG content: 1.4282%
04	-do-	-do-	C231	LHR-11-23-000054	EG content: 1.2158%
05	-do-	-do-	J242	LHR-11-23-000039	EG content: 1.2366%
06	-do-	-do-	D224	LHR-11-23-000041	EG content: 1.3484%
07	-do-	-do-	G204	LHR-11-23-000037	EG content: 1.6828%
08	Allergo Syrup 60ml	-do-	L210	LHR-11-23-000040	EG content: 1.4933%
09	Mucorid syrup	-do-	C227	LHR-11-23-000029	EG content: 9.8709%
10	-do-	-do-	B224	LHR-11-23-000028	EG content: 14.9891%
11	-do-	-do-	B201	LHR-11-23-000030	EG content: 17.5004%
12	-do-	-do-	C210	LHR-11-23-000031	EG content: 14.4483%
13	-do-	-do-	A210	LHR-11-23-000047	EG content: 12.7868%
14	-do-	-do-	B225	LHR-11-23-000032	EG content: 10.9240%
15	-do-	-do-	A230	LHR-11-23-000033	EG content: 12.0895%
16	Ulcofin syrup	-do-	B209	LHR-11-23-000027	Complies with standard
17	-do-	-do-	L218	LHR-11-23-000046	Complies with standard
18	Lorate suspension	-do-	J210	LHR-11-23-000049	EG content: 1.9558%
19	Iropal syrup	-do-	H225	LHR-11-23-000052	EG content: 12.8300%

07. Furthermore, Therapeutic Goods Administration (TGA) Australia has also declared the presence of said impurities in samples sent to them for the purpose of test/analysis by Maldives Food and Drug Authority, Maldives.

08. In the light of above-mentioned, the division of QA&LT, issued letter for suspension of production in the oral liquid section and show-cause notice to M/s. Pharmix Laboratories Lahore vide letter 03-41/2023-QC dated 08-12-2023.

09. M/s. Pharmix Laboratories Lahore vide letter dated 30-12-2023 has made following submissions:

"(1) Before receiving Lab Test reports from anywhere, we recalled all Liquid syrup & suspension batches manufactured in the year 2022 which even were not mentioned in DRAP Alert No. No l/S/11-23-40 and complete recall data is attached herewith.
(2) On 08-11-2023, our Maldivian importer informed that MFDA is suspecting EG/DEG impurity in Alergo Syrup but still the batch number has not been declared and when MFDA will confirm the Batch number, they will inform us. On receiving this information, we immediately sent samples of our Alergo Syrup batch K222 to PCSIR for EG/DEG testing as we were not aware about the batch number reportedly suspected by MFDA, so we sent samples to PCSIR of the Last batch which we exported to Maldives. We received report from PCSIR Labs on 21-11-2023 that No DEG/EG impurity has been detected (PCSIR report of Alergo Batch K222 which was manufactured in 2022 is attached) whereas for the same Alergo Batch Number K 222 mentioned in MFDA Alert reports that EG is present (Copy is attached).
(3) The CDL reports for batch numbers B220 & L210 of Alergo Syrup state that both DEG & EG impurities are present while WHO has mentioned that as per TGA Australia only EG impurity is present for the both above batches.
(4) Your kind self know that in liquid manufacturing whole of the batch manufacturing process is completed in ONE CYCLE ("batch" means a quantity of any drug produced during a given cycle of manufacture;). At the Packing Stage companies pack in 60 ml & 120 ml as per their market need. DRAP officials took samples of Alergo Syrup Batch No L210 in both pack sizes i.e. 60ml & 120 ml to send to CDL. On receiving the reports, we found that in 60 ml pack sample CDL Lab result, DEG Was Not detected WHILE in 120ml pack size, both DEG & EG were detected WHEREAS in both reports of 60 & 120 ml, the value of EG were also different and can be checked in CDL Reports.
(5) On 06-12-2023 we sent Alergo Syrup Batch number J242 to PCSIR for DEG & EG testing. PCSIR report declares that there is No DEG/EG impurity in Glycerin & Propylene glycol used (Report is attached) while for the same batch number J242 Sample, CDL declared that EG impurity is Present. Respected Sir, we respectfully want to express that quantification of DEG/EG impurity from the Finished pharmaceutical product is different because your kindself know that in finished products other than solvents (sorbitol, glycerin & propylene glycol) some other excipients and different API are also present and without analyzing /extracting on individual excipients, the lab results could be perplexing.
*(6) Sir, the reference limit (0.1%) mentioned on CDL reports are for individual solvents (Glycerin. Propylene glycol & Sorbitol) Not For The finished pharmaceutical products. Regarding Finished Pharmaceutical Products limits, we humbly request you to please check below mentioned Allowable Threshold of DEG & EG which is 0.5 mg/Kg Body weight per day. (Jakarta Indonesia BPOM reference - A PIC/S member country regulatory body (*https://picscheme.org/en/members*)*
(7) We are in syrup manufacturing since more than 12 years and by the grace of Allah SWT hundreds of thousand packs of our manufactured syrups have been safely consumed in Pakistan and in other countries. We are in practice to perform pharmacovigilance, Adverse reporting data forms of different products from doctors of different cities of Pakistan. Adverse drug reporting forms of Mucorid and Alergo syrup are attached here with (thanks to Allah SWT no Adverse reaction has been reported- ADR data is attached).
(8) Sir, Pakistan Pharmacopoeia, European Pharmacopeia 10th addition & BP 2023 clearly state that ONLY GLYCERIN should be tested. Whereas European Pharmacopoeia Commission (EPC) has just revised monograph on Propylene glycol in November 2023 (Pharmacopoeial Test References Are Attached) while we started tests for the impurities of solvents (Sorbitol, glycerin, Propylene glycol) by TTI Labs & PCSIR before any alert and in this regard want to bring in your kind knowledge that the current lots of Solvents (Sorbitol, Glycerin and Propylene glycol) present in our warehouse have also been sampled by respected Federal Inspector of drugs Lahore which has been declared Standard Quality by CDL (Reports are attached)."

10. Keeping in view the above-mentioned facts, representatives of firm are called before the Board for personal hearing.

Proceedings and decision of 335th meeting of the Board:

11. In compliance to the show cause and personal hearing letter issued, Dr. Shahzad Ahmad, Director and Mr. Fayyaz Ahmad, Director of M/s. Pharmix Laboratories Lahore appeared before the Board. The representatives of the firm raised concerns regarding the testing method adopted by the Central Drugs Laboratory Karachi and assured the Board that they have revised their procedures so that such incidents could not occur in future. The Board after thorough deliberations, considering the facts of the case and keeping in view the submission made by representatives of M/s. Pharmix Laboratories Lahore decided as under:

i. The division of QA&LT to conduct a GMP inspection of firm by a panel nominated by the Director (QA&LT) at the earliest as the production has been resumed which was suspended by the QA Division on 08-12-2023
ii. Destruction of stocks recalled by the firm. The process of destruction of stocks will be carried out in the presence of area FID Lahore or a person nominated by the Additional Director DRAP Lahore. The area FID Lahore or the nominated person will submit a detailed report of the process to the division of QA&LT.
iii. In addition, the board directed the QA division to revise the advisory regarding the testing of EG & DEG and allow the testing from all WHO prequalified labs and CDL, Karachi

Case No. 02: SUBSTANDARD MULTIVITAMIN SYRUP B. NO. J19:081 MANUFACTURED BY M/S. NAWABSONS LABORATORIES, JIA BAGGA OFF RAIWIND ROAD, LAHORE – QCB ISLAMABAD CASE.

01. Secretary Quality Control Board Islamabad vide letter vide F. No. 18(1)-QCB/ICT/2012/726 dated 22-02-2022 forwarded the case of manufacturing of Substandard Multi Vitamin Syrup 120ml Batch No. J19:018 Manufactured by M/s. Nawabsons Laboratories Lahore. Brief facts of the case as under:
i. Inspector of Drugs Islamabad, during inspection of District Population Welfare Office G-9 markaz Islamabad drew samples of Multi Vitamin Syrup 120ml Batch No. J19:018 manufactured by M/s. Nawabsons Laboratories Lahore for the purpose of test/analysis.
ii. DTL Rawalpindi declared the said batch of Multi Vitamin Syrup as "Substandard" on the basis of assay.
iii. The accused were called before Quality Control Board Islamabad in its 50th meeting but no one appeared before the Board.
02. In view of above-stated facts, Quality Control Board Islamabad in its 50th meeting held on 30-12-2021 decided as under:

> *"The nominated accused did not appear before the Board. The Board considered the facts available on record and decided to refer the case to the Drug Registration Board for cancellation of registration of drug i.e. Syp. Multi Vitamin of M/s Nawabsons Laboratories, Lahore after fulfillment of all legal formalities in this regard."*

03. Secretary, Quality Control Board Islamabad in above-mentioned decision has requested the Registration Board for cancellation of Syp. Multi Vitamin 120ml, Reg. No. 004929 manufactured by M/s. Nawabsons Laboratories Lahore.

Proceedings and Decision of 320th meeting:

04. The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board:

05. Registration Board after discussion, considering the facts of the case decided:
"To issue show cause notice to M/s. Nawabsons Laboratories Lahore for manufacturing and sale of Substandard product "Multi Vitamin Syrup 120ml Batch No. J19:018" under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration."
06. In compliance of the above-mentioned decision of the Board, Show cause letter vide F. No. 03-45/2022-QC(321-RB) dated 15-09-2022 was issued to M/s. Nawabsons Laboratories Lahore to which the firm vide Ref. No. NSL/2022/9110-9113 dated 22-12-2022 replied that they have never manufactured batch No. J19-018 of their product namely "Multivitamin Syrup" and suspected that the report product may be spurious, Moreover, the firm informed that they never received warrantor / Manufacturer portion of sample taken, copy of Government analyst report and details of the sample taken.
07. In light of reply submitted by the firm, letter vide F. No. 03-13/2022-QC dated 10-01-2023 and 25-10-2023, reply of firm was forwarded to the Secretary QCB Islamabad. In response, the Secretary QCB Islamabad vide letter F. No. 18(1)-QCB/ICT/2012/27 dated 30-10-2023 provided the following documents:

- Copy of warrantor/manufacturer portion
- Copy of warranty for Batch No. J19:081 for syrup Multivitamin issued by the manufacturer i.e. M/s Nawabsons Laboratories (Pvt) Ltd.
- Government analyst report of DTL Rawalpindi
- Sampling details
- Copy of letter bearing the subject provision of test report/necessary information to M/s. Nawabsons Laboratories (Pvt) Ltd

08. The Secretary QCB Islamabad further informed that the batch number of substandard multivitamin syrup was mistakenly written as J19:018 whereas the correct batch number is **J19:081**. Therefore, in the light of above-mentioned reply, M/s. Nawabsons Laboratories (Pvt.) Ltd., Lahore was once again show caused vide letter 03-13/2022-QC dated 22-12-2023 along with the copy of reply submitted by the Secretary QCB Islamabad.

09. In response to above-mentioned show cause notice, M/s. Nawabsons Laboratories Lahore has provided a reply vide Ref. No. NSL/2024/9242-43 dated 13-01-2024 wherein the firm still denies that they have manufacture batch J19:081. However, the firm has stated that they have manufactured batch No. J18:081 of their product in question and has provided copy of warranty issued to M/s. Health tech International Rawalpindi for stated batch along with picture of sample portion received to them from Senior Drug Inspector Islamabad.

10. On evaluation of copies of warranty provided by Secretary QCB Islamabad and M/s. Nawabsons Laboratories Lahore, it is observed that both parties have provided the same warranty vide invoice No. 23188, for order No. 2514, dated 28-June-2018 and issued to M/s. Health Tech International Rawalpindi however, due to illegibility of the provided copy, the confusion regarding batch number may have occurred that can further be verified from the pictures of manufacturer portion provided by the firm.

11. Keeping in view the above-mentioned facts, representatives of firm are called before the Board for personal hearing.

Proceedings and decision of 335th meeting of the Board:

12. In compliance to the show cause and personal hearing letter issued, Dr. Imran Mehmood Chaudhary Advocate, Legal Advisor of M/s. Nawabsons Laboratories Lahore appeared before the Board. The representative of the firm endorsed the reply already submitted by the firm.

The Board after thorough deliberations, considering the facts of the case and keeping in view the submission made by representative of M/s. Nawabsons Laboratories Lahore decided as under:

i. Suspension of the Registration of Multivitamin Syrup, Registration No. 004929 of M/s. Nawabsons Laboratories (Pvt.) Ltd., Jia Bagga, Off Raiwind road, Lahore for six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by panel with satisfactory report; whichever is later.

ii. A panel constituted by the Director QA/LT division will conduct a risk-based inspection of firm including the product specific aspects of RCA and CAPA submitted by firm in the light of test /analysis report of CDL regarding all quality attributes of product which are declared non- compliant.

Case No. 03: SUBSTANDARD MENTIN FORTE TABLET MANUFACTURED BY M/S. UNEXO LABS LAHORE – QCB ISLAMABAD CASE.

01. Secretary Quality Control Board Islamabad vide letter vide F. No. 18(1)-QCB/ICT/2012/722 dated 22-02-2022 forwarded the case of manufacturing of Substandard Mentin Forte Tablet Batch No. MT80 Manufactured by M/s. Unexo Labs (Pvt.) Ltd., Lahore. Brief facts of the case as under:

i. Inspector of Drugs Islamabad, during inspection of District Population Welfare Office G-9 markaz Islamabad drew samples of Mentin Forte 625mg tablet Batch No. MT80 manufactured by M/s. Unexo Labs Lahore for the purpose of test/analysis.

ii. DTL Rawalpindi declared the said batch of Mentin forte tablet as "Substandard" on the basis of assay.

iii. The accused were called before Quality Control Board Islamabad in its 50th meeting but no one appeared before the Board.

02. In view of above-stated facts, Quality Control Board Islamabad in its 50th meeting held on 30-12-2021 decided as under:

> *"The nominated accused did not appear before the Board. The Board considered the facts available on record and decided to refer the case to the Drug Registration Board for cancellation of registration of drug i.e. Tab Mentin Forte (Co Amoxiclav) of M/s Unexolabs, Lahore after fulfillment of all legal formalities in this regard."*

03. Secretary, Quality Control Board Islamabad in above-mentioned decision has requested the Registration Board for cancellation of tablet Mentin Forte, Reg. No. 023923 manufactured by M/s. Unexolabs Lahore.

Proceedings and Decision of 320th meeting:

04. The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

05. Registration Board after discussion, considering the facts of the case decided:

"To issue show cause notice to M/s. Unexolabs Lahore for manufacturing and sale of Substandard product "Mentin Forte Tablet Batch No. MT80" under clause (c) and (d) of sub

section 11 of section 7 of the Drugs Act 1976for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration."

06. In the light of decision of decision of Board, the accused were issued showcause notice vide letter F. No. 03-45/2022-QC(321-RB) dated 15-11-2022. In response to said showcause, M/s. Unexo Laboratories Lahore vide letter Ref. UL/Mentin Forte/MT80 dated 29-11-2022 replied as under:

"Dear Sir,

With reference to your letter no. ***F. No. 3-45/2022-QC (321-RB),*** *dated 15th November 2022 and subject matter. We would like to bring to your kind attention the following points.*

1. The Inspector of Drugs ICT, Islamabad sampled the product ***Tab. Mentin Forte (Batch MT80)*** *from the Main Stores District Population Welfare office, Islamabad, on* ***24.07.2017*** *for the purpose of test and analysis.*

The sample was received by DTL, Rawalpindi on ***26th July 2017.***

The reporting date on the ***DTL Report No.TRA. 01-07001941/DTL is 22nd November 2017.*** *This is a period of* ***4 months*** *from receipt of sample by DTL and its analysis. Drug Act 1976 stipulates a time of* ***60 days*** *within which the DTL has to report the results of the sample analysis. This makes the DTL Report* ***No.TRA. 01-07001941/DTL time barred.***

2. For the sake of argument if we consider the letter No. ***SMR49/DTL/RWP/2017, dated 16.08.2017*** *sent to us by* ***DTL, Rawalpindi,*** *intimating to send the method of analysis of Mentin forte Tablet.*

We sent the required information to DTL, Rawalpindi via letter No. ***UL/786/2017/Mentin****, dated* ***25.08.2017*** *by courier.*

The maximum time a letter sent by courier takes ***4 days*** *to reach the destination. So assuming the letter reached DTL by* ***30.08.2017.***

The DTL, Rawalpindi should had conducted the test at the maximum by ***29th October 2017****. But in this case the DTL Report No.* ***TRA. 01-07001941/DTL*** *is dated* ***22nd November 2017****. That is also outside the stipulated time limit of 60 days as required by Drug Act 1976, making the DTL Report No.* ***TRA. 01-07001941/DTL time barred.***

3. We were not given the opportunity to request for retesting for our product Mentin Forte Tablet (Batch No. MT-80) from appellate laboratory, as per Drugs Act 1976 and the law/rules framed thereunder. Reason being that we were not furnished with the required documentation to completely scrutinize the case before requesting for retest. We were furnished with the required documentation in parts by the Drug Inspector ICT, Islamabad after our repeated requests.

Still to date we have not been furnished with the copy of invoice/warranty from the store keeper of main store, District Population Welfare office, Islamabad as proof of purchase.

4. We repeatedly informed the Inspector of Drugs, ICT, Islamabad, that ***M/S. Mediwise Pharma is not our authorized distributor****, who supplied the Mentin Forte (Batch MT-80) to District Population Welfare Office.*

The storage conditions of the said Distributor ***M/S. Mediwise*** *are not known, as well as the storage conditions of District Population Welfare office, Islamabad, Improper storage affects the stability of the product.*

Subsequently, we cannot be held responsible for the condition of the product supplied by an unauthorized distributor with unknown credentials and storage conditions.

In the light of the above facts, it is kindly requested for a considerate look at this case and to dismiss it.

That our such request is in line with our rights of fair defense and in the interest of justice as well as to ensure the adherence and compliance with the legal mandates and stipulations.

Kindly find attached the copies of correspondence with Inspector of Drugs ICT, Islamabad and DTL, Rawalpindi."

07. Reply of the firm was communicated to Secretary QCB Islamabad vide letter F. No. 03-14/2022-QC dated 13-01-2023. Secretary QCB Islamabad vide letter F. No. 18(1)-QCB/ICT/2012 dated 27-11-2023 responded to the queries raised by firm as under:

"[…] 2. It is pertinent to mention here that the Tab. Mentin Forte Batch No. MT80 manufactured by M/s Unexo Labs (Pvt) Ltd, was declared Sub-standard by the DTL. Furthermore, the sample was drawn from main stores/warehouse of District Population Welfare Office, Islamabad.

3. The response of queries is written as;

i. *DTL had requested for time extension for testing of samples, that was issued accordingly by the Quality Control Board, Islamabad.*
ii. *No such request regarding appellate testing was ever received by this office or Quality Control Board;*
iii. *Copy of invoice from District Population Welfare Office is attached.*
iv. *The complete supply chain evidence of Mentin Forte Tablet, Batch No. MT80 is attached herewith."*

Proceedings and Decision of 333rd Meeting of Registration Board:

08. The matter was presented before and was thoroughly deliberated by the Board. Keeping in view the stance submitted by firm and reply of Secretary QCB Islamabad the Board decided as under:

i. Call the firm before the Board for a chance of personal hearing.
ii. Invite the Secretary QCB Islamabad in forthcoming meeting of the Board to provide assistance to Board in the matter at hand.

09. Keeping in view the decision of the Board, representatives of firm are called before the Board for personal hearing.

Proceedings and decision of 335th meeting of the Board:

In compliance to the show cause and personal hearing letter issued, Mr. Muhammad Ishtiaq Javed Advocate, Legal Advisor of M/s. Unexolabs (Pvt.) Ltd., 9.5 Km, Sheikhupura Road Lahore appeared before the Board. The representative of the firm endorsed the reply already submitted by the firm. The Board after thorough deliberations, considering the facts of the case and keeping in view the submission made by representative of M/s. Unexolabs (Pvt.) Ltd., Lahore decided as under:

i. Suspension of the Registration of product namely Mentin Forte tablet, Registration No. 023923 of M/s. Unexolabs (Pvt.) Ltd., 9.5 Km, Sheikhupura Road Lahore for six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by panel with satisfactory report; whichever is later.
ii. A panel constituted by the Director (QA&LT) will conduct a risk-based inspection including the verification of product specific aspects of RCA and CAPA submitted by firm in the light of test /analysis report of CDL regarding all quality attributes of product which are declared non- compliant. The board also directed to include representative of ICT, Health Department, Islamabad.

Case No. 04: MANUFACTURING AND SELLING 12922 PACKS OF NAZE 10ML DROPS BY M/S SCHAZOO PHARMACEUTICAL LABORATORIES (PVT) LTD WITHOUT APPROVED LIQUID (PSYCHOTROPIC) SECTION.

BACKGROUND:

A communication was received from M/s Schazoo Pharmaceutical Laboratories (Pvt) Ltd., Sheikhupura, regarding their application for the allocation of Clonazepam quota for manufacturing their registered products for the year 2024. The application underwent evaluation as per standard operating procedures (SOP) for quota allocation of controlled substances, revealing several deficiencies including ***manufacturing and selling 12922 packs of Naze 10ml drops without clarification on QA/retention samples. Lack of a notarized copy of the consumption certificate for the last allocated quota. Absence of a notarized approval for the Liquid (Psychotropic) Section despite manufacturing and selling Naze 10ml drops. Inadequate record-keeping for physicians' samples in the routine quota for the year 2023***.

To address these deficiencies, the firm was required to submit a response accordingly, the firm had submitted response to the deficiencies mentioned, which were evaluated by the scrutiny committee. It was noted that the firm does not have approval from the Central Licensing Board (CLB) for the Liquid (Psychotropic) Section to manufacture Naze Drops. Consequently, the case was referred to the Central Allocation Quota Committee (CAQCS) for further deliberation. In its meeting, the CAQCS allocated 27.05 Kg of clonazepam to the firm but advised the Drug Regulatory Authority of Pakistan (DRAP) to investigate the matter further An allocation letter has been issued to the firm, the case be referred to the Division of Quality Assurance & Licensing Technology (QA & LT) for information and necessary action.

ACTION TAKEN BY CONTROLLED DRUG DIVISION:

The Controlled Drug Division reviewed the findings and identified shortcomings in the firm's application for the allocation of Clonazepam quota. Deficiencies stated above, including unclear clarification on quality assurance/retention samples for Naze 10ml drops, missing notarized consumption certificates, absent approval for Liquid (Psychotropic) Section, and inadequate record-keeping for physicians' samples. The division referred the case to the Quality Assurance & Lab Testing (QA&LT) Division for necessary action.

ACTION TAKEN BY QA&LT DIVISION & RESPONSE OF FIRM:

The QA&LT Division initiated correspondence with Schazoo Pharmaceutical Laboratories Pvt Ltd to address the identified deficiencies. Requests were made for compliance reports and corrective action plans. Letters was

issued regarding the queries were raised on the utilization of Clonazepam. The firm had submitted their response, wherein they have responded to each query raised by the QA&LT Division, which has been reproduced hereunder:-

" I. It is submitted that the quota allocated by DRAP vide letter # F.5-2/2023-CD (Clonazepam-04) (M-86), dated 23.02.2023 clearly states that allocated quota i.e. 23.43 Kg of Clonazepam have been allocated for manufacture of drugs containing Clonazepam registered in our name. Under these circumstances, Naze oral solution is part and parcel of the allocated quota and it is registered with DRAP holding valid drug registration no. 053501.

We've utilized 375 grams of Clonazepam from the total quota of 23.43 Kg, which accounts for 1.60% of the total quota. The BMR is enclosed for your convenience and reference. Quota letter # F.5-2/2023-CD (Clonazepam-04) (M-86), dated 23.02.2023, and BMR copy as "(Enclosure I-II)

II. We have a valid drug import license for Clonazepam to be used for the solution. (Enclosure III).

III. At the time of application of quota allocation under our letter # SPL/NOR/23 (C), dated; 05.01.2023 and in Undertaking for licit manufacturing of controlled substance it was submitted which included our three registered products NAZE 0.5mg TABLETS, NAZE 2mg TABLETS & NAZE ORAL DROPS, Registration # 050856, 050857 & 053501. Application of Quota letter # SPL/NOR/23(C), dated 05.01.2023, and Undertaking for Licit Manufacturing (Enclosure IV-V1)

IV. We wish to update that we recently participated in the 14th Pediatric Neurology. Conference, 2023, held from June 16-18, 2023, and have enclosed evidence of our participation. During the conference, concerns were raised by several pediatric doctors regarding the unavailability of Clonazepam Oral Drops in the market for children diagnosed with epilepsy. Presently, only two companies, Rivotril (Martin Dow) and our company, hold registration for Clonazepam oral drops. At that time, Martin Dow was encountering difficulties in importing the said drops due to hardship cases.

In response to the urgent requests from pediatric doctors, as evidenced by the enclosed request letters, and acknowledging the shortage of the product in the market, we manufactured a limited batch of Oral Naze drops. Despite the product incurring losses, we address the needs of children suffering from epilepsy who may not be able to take the medication in tablet form.

It is crucial to emphasize the need for the substance in drop form, especially for infantile patients diagnosed with epilepsy, as determined by the treating doctor. Failure to entertain the requests of doctors at that time could have led to dissatisfaction among medical professionals and a lack of support for needy patients.

This decision was made on humanitarian grounds and aligns with the decision passed in the 287th meeting of the Central Licensing Board, a copy of which is enclosed. The Central Licensing Board recently decided that psychotropic products can be manufactured in general areas, eliminating the need for a segregated psychotropic section. However, as deliberations are ongoing, we have not proceeded to manufacture any further batches .We appreciate your understanding and support in this matter, and we remain committed to addressing the critical needs of patients , particularly those with pediatric epilepsy.

Copies of evidence of participation in 14th Pediatric Neurology Conference 2023 along with doctor request letters for the availability of Naze oral drops and 287th minutes of the meeting are enclosed as (Enclosure VI-VII-VIII)

Without any prejudice to the submission made hereinabove, it is essential to submit that the inadequate quantity in the market shall result in the cancellation/suspension of the registration granted to the company by Drug Regulatory Authority of Pakistan as envisioned undersection 7(11) of the Drugs Act, 1976.Further, Presently, only two companies, Rivotril (Imported and distributed by Martin Dow) and our company, hold registration for Clonazepam oral drops and both brands are not available in Pakistan it may be noted that the product is essentially used for the treatment of epilepsy diagnosed in children.

V. Explicit permission to re-appropriate the usage of Clonazepam forthe production of Naze oral solution could be sought due to humanitarian groundsfor very needy kids as no other company has valid registration except us.

VI. We have submitted the production intimation to FID for the use of Clonazepam for Naze oral liquid solution vide our letter no. SPL-NOR-43-23, dated: 19.06.2023 that duly received by DRAP Lahore office on dated: 20.06.2023 (Enclosure-IX)

VII. Valid copy of Drug registration letter of Naze oral drop. (Enclosure-X)
VIII. Valid copy of DML is enclosed (Enclosure-XI)".

RECOMMENDATIONS BY QA&LT:

Division of Licensing was requested to provide the details whether M/s Schazoo Pharmaceutical Laboratories (Pvt) Ltd., has been granted approval for Section of Liquid (Psychotropic) Section from the Central Licensing Board (CLB), to manufacture Naze Drops or not and Division of Licensing responded that the firm does not have approval from the Central Licensing Board (CLB) for the Liquid (Psychotropic) Section to manufacture Naze Drops. Considering the severity of the identified deficiencies and the importance of maintaining pharmaceutical quality and safety standards, the QA&LT Division recommends a thorough deliberation on the matter. This includes convening a personal hearing with Schazoo Pharmaceutical Laboratories (Pvt) Ltd., to provide them with an opportunity to present their perspective and address the regulatory concerns directly. Additionally, the division suggests exploring further investigative actions and potential recommendations for corrective measures to ensure the firm's compliance with GMP standards.

Proceedings and decision of 335th meeting of the Board:

The Board acknowledged and approved the firm's request for an adjournment, taking into account the unavailability of their representative, Mr. Asad Shuja ur Rehman. A hearing will be scheduled promptly to address regulatory concerns regarding M/s Schazoo Pharmaceutical Laboratories (Pvt) Ltd.'s approval status for Naze Drops manufacturing.

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